

# Exhibit 50

# Exhibit 50

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**ORTHO BIOTECH**

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700 U.S. Highway 202  
P.O. Box 670  
Raritan, NJ 08869-0670

November 30, 2000

To: All Ortho Biotech Employees:

As a manufacturer of diversified health care products, Johnson & Johnson conducts a wide range of research, medical education, marketing and selling activities - each of these activities is affected by a variety of legal and ethical standards. Compliance with these standards is consistent with our commitment to the Credo and will enable us to protect our customers, Ortho Biotech, and ourselves from scrutiny. J&J Legal has prepared the Health Care Regulatory Guidance Documents for Promotional and Marketing Practices which were developed to help us comply with the Fraud and Abuse laws. The creation of the Ortho Biotech **Best Practice Guidelines** manual provide us with a set of tools designed to help us comply with these regulations in an efficient and helpful manner.

Successfully operating within the laws that regulate our business while striving to reach our destination faster, more efficiently and ahead of the competition demands a commitment to compliance and awareness of key regulations. This initiative plays a vital role in our ability to do this, and is critically important to our overall business strategy and success.

Health care compliance provides us an opportunity to protect the customer, ourselves, and Johnson & Johnson. Simply stated, health care compliance "*makes sense*". It is up to each one of us to take on a leadership role in adhering to these Guidelines, and supporting the values of this program. I urge everyone to read the Ortho Biotech Guidelines and use the information and material provided to support the creation of successful and appropriate business practices.

Gary

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# ORTHO BIOTECH

## INTRODUCTION

The OBI Best Practice Guidelines was prepared by a team of seasoned, experienced OBI Managers/Directors with the assistance of J&J Legal. Our team included key management from each of our Sales & Marketing Franchises, and all functional areas of the company.

The guidelines are designed to provide you with a simple, straightforward description of the regulations with emphasis on OBI's unique practices. In addition, each section contains key process steps with applicable forms/templates to enable you to implement the guidelines in an efficient and effective manner.

Each section also provides common issues/questions that relate to OBI's business practices.

The Health Care Compliance Department will be another resource you can call on to help answer questions and clarify regulations.

Ultimately, each of us must take full responsibility for the compliance decisions we make. This will require strong leadership and sound judgement. We trust you will use this resource to help you make the right decisions.

OBI Health Care Compliance Team

November, 1999

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# ORTHO BIOTECH

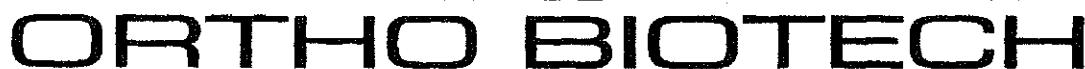
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## HEALTH CARE COMPLIANCE BEST PRACTICE GUIDELINES

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Arrangements to Obtain  
Consulting and Other Services  
from Customers Section 1



## Arrangements to Obtain Consulting and Other Services from Customers

### Overview

Given a legitimate need, OBI may obtain consulting or other services from customers or healthcare professionals. The relationship must be properly documented in a written agreement and the compensation paid consistent with fair market value of the services rendered. Consulting Agreements must be completed for research-related services (e.g. bona fide clinical studies), training services (e.g. clerkships, preceptorships, design and development of J&J products, training schools), educational materials or disease management programs, speaker programs and advisory boards. "Grants" involve financial support for activities that are not being performed primarily on behalf of OBI (see Section #3 on Educational Grants/Research Grants/Speaker Programs).

### Policy and OBI Procedures

OBI may obtain consulting and other services from customers, healthcare professionals, or through third party vendors. Under all arrangements, service/consulting agreements are appropriate for the following activities:

- Research-related services
- Speakers
- Advisory Boards
- Communication Programs
- Training services
- Development of educational materials, disease management programs or software programs
- Patient compliance programs
- Independent contract sales organizations

To obtain guidance and written agreement templates appropriate for a specific situation, contact the OBI Health Care Compliance (HCC) department.

Clerkships/preceptorship templates are available from the sales training department through OBI\*Net.

See Arrangements to Obtain Consulting and Other Services from Customers process flow in Section 1-5.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.***

**OBI Related Documents, Templates and Forms**

- Consulting and Service Agreement Checklist
- Preceptorship Confirmation Letter
- Speaker Confirmation Letter
- Clerkship confirmation Letter
- Clerkship/Preceptorship Guidelines for Product Specialists
- Master Consulting Agreement
- Clinical Study Agreements (See the Clinical Affairs Department for these documents)

**Questions and Answers**

**Q1:** Do I need a consulting agreement for a one-time preceptorship?

**A1:** Yes. A written agreement is required for all services paid for by OBI. We make no exception for one time meetings or those involving small dollar amounts.

**Q2:** Are all consulting agreements maintained by the HCC Department?

**A2:** Yes. We must be able to track and audit the entire relationship we have with each healthcare professional we use as a consultant.

**Q3:** Business Development has an agreement with Dr. Jones to run a panel meeting, and R&D wants Dr. Jones's opinion on a new product design. Does OBI need a second separate consulting agreement?

**A3:** Yes. If the scope of the additional services are different than the original agreement. All services and payments must be made pursuant to a written agreement for those services at issue.

**Q4:** May I prepare my own consulting agreement?

**A4:** Yes. However you must use one of the standard template/agreements or contact the HCC Department for approval of any changes to the standard templates.

**Q5:** May I offer a consultant a signing bonus?

**A5:** No. Before beginning any negotiation, you should familiarize yourself with the guidelines regarding fair market value compensation and speak with the HCC Department.

**Q6:** Are meals and entertainment related to discussing consulting projects subject to the Entertainment/Meals guidelines?

**A6:** Yes.

**Q7:** Can clinical trial investigators/participants seek reimbursement from third party payors, including Medicare or Medicaid, for free drug provided for a clinical trial?

**A7:** No. Reimbursement for the distribution, use, or administration of free drug supplied by OBI for clinical trials cannot be sought from third party payors.

**Q8:** Do I need a consulting agreement for a one-time speaker (e.g. at a local meeting)?

**A8:** Yes. A written agreement is required for all services paid for by OBI. There is no exception for one-time meetings or those involving small dollar amounts.

**Q9:** Is a confidentiality agreement sufficient for an advisory meeting?

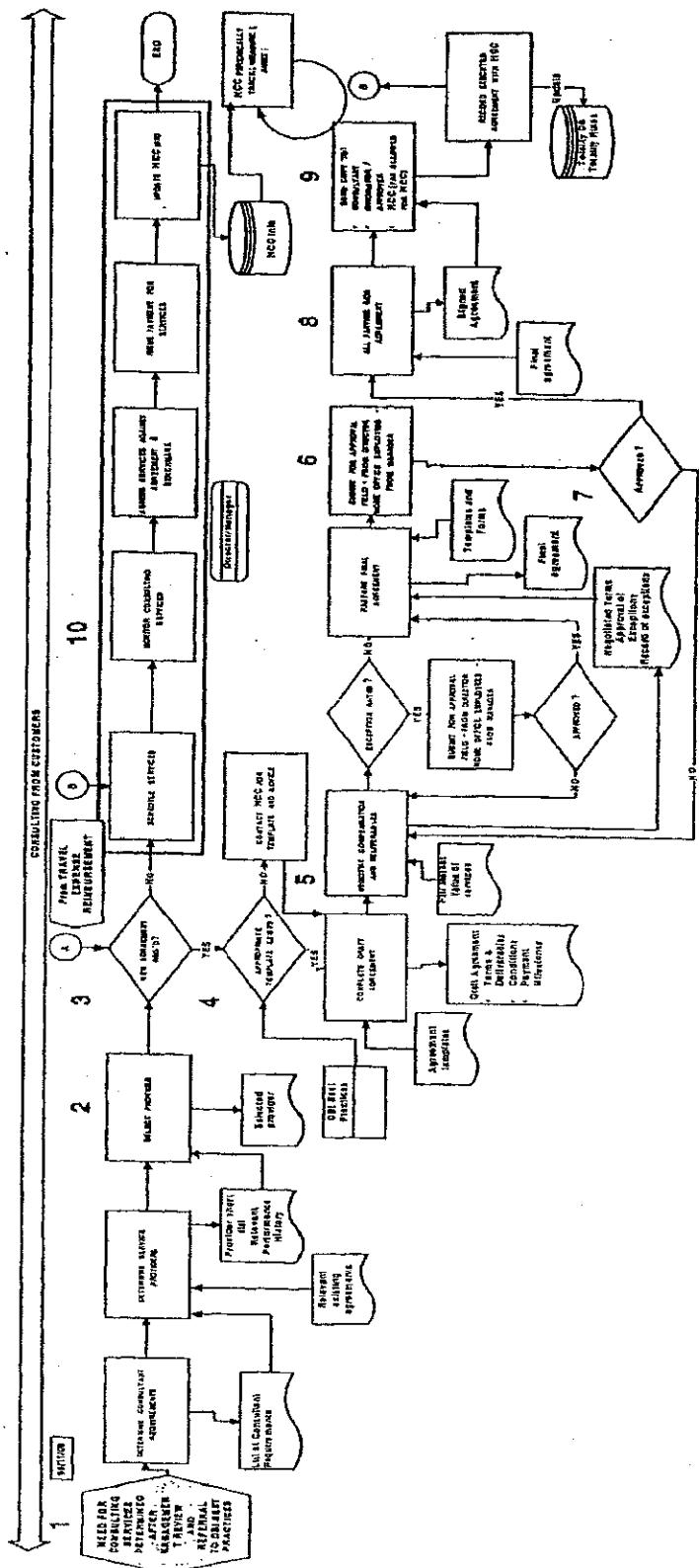
**A9:** No. You need both a confidentiality agreement if proprietary information is shared, and you also need a consulting agreement that delineates services to be rendered. In most cases, the confidentiality agreement is contained within the consulting agreement.

**Q10:** Can OBI contract with a customer to develop a program on anemia?

**A10:** Yes. Also, as part of the consulting arrangement to develop educational programs, OBI must also obtain licenses or other rights to the materials that are developed.

**More Information**

- Arrangements to obtain Consulting and Other Services from Customers Guideline #1
- Educational Grants/Research Grants/Speakers Programs Guideline #3
- Site Visit Guideline #9
- Entertainment and Gifts Guideline #10
- Travel Expense Reimbursement Guideline #11



## Consulting From Customers Key Process Steps

- 1- Determine if there is a need for consulting services after reviewing with managers and checking guidelines
- 2 - Select the consultant after determining the necessary requirements
- 3 - Determine if a new agreement/addendum is required
- 4 - If a new agreement is required determine if a new template is required
- 5 - Negotiate compensations and deliverables
- 6 - Submit for approval:
  - Field - RBD
  - Home Office - MGR
- 7 - Obtain approval or renegotiate the agreement
- 8 - Once approval is obtained have all parties sign the agreement
- 9 - Send the agreements to all parties and HCC
- 10 . Schedule, monitor, pay, and report on services

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**OBI Related Documents, Templates and Forms**

**Consulting and Service Agreement Checklist**

	<u>YES</u>	<u>NO</u>
Does the arrangement involve a service of legitimate interest or need to the company?		
Does the consultant possess special skills or information of interest to OBI?		
Is there a written agreement?		
Is the agreement signed by the parties?		
Does the agreement describe the consultant's special capabilities?		
Does the agreement specify the duration of the arrangement?		
Does the agreement include a detailed description of the services to be performed?		
Does the agreement specify how performance or completion of the project will be measured for purposes of payment?		
Will the consultant be paid under a flat fee, daily rate, hourly rate, or similar structure and not on a per patient or percentage basis?		
Have you evaluated whether the aggregate value of the compensation is consistent with the fair market value of the services to be provided under the agreement?		
Is the payment to be withheld pending a showing that the consultant actually performed the required services?		
Has a specific OBI employee been designated as responsible for administration and monitoring of performance under the contract?		
Is the agreement consistent with any specific guidelines applicable to the subject matter involved?		
Have all legal issues as well as any deviations from this Guidance Document (e.g., any percentage payment arrangements) been cleared with the Law Department?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT TO COMPLY WITH THE GUIDELINES OR CONSULT THE HCC DEPARTMENT BEFORE PROCEEDING.**

**PRECEPTORSHIP CONFIRMATION LETTER**

Healthcare Professional (HCP)  
(Addressee)

Dear (HCP):

Thank you for agreeing to host the participants for the upcoming preceptorship program.

The dates and times along with the names of the participants are as follows:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

The purpose of the preceptorship is educational in nature, namely to learn about the use of our products and your requirements associated with these products, not to sell PROCRIT® or any other Ortho Biotech, Inc. products.

The honorarium for assisting with this education is \_\_\_\_\_ per Product Specialist per day, which includes meals, etc. Attached is a copy of the OBI Clerkship Guidelines that the Product Specialists have been instructed to follow.

Please sign this letter as confirmation of your agreement.

Sincerely,

**Training Manager**

Agreed and accepted:

(HCP) Signature and Date

Please forward copies to each of the following:

- 1) The Consultant (HCP)
- 2) The HCC Department
- 3) Originator of agreement

**SPEAKER CONFIRMATION LETTER**

Healthcare Professional  
(Addressee)

Dear (HCP):

Thank you for agreeing to speak at our upcoming \_\_\_\_\_ Training School for Ortho Biotech Product Specialists.

The topic of your presentation is \_\_\_\_\_. The talk is scheduled for \_\_\_\_\_ Date/Time \_\_\_\_\_. Attached is a copy of the lecture. I would greatly appreciate it if you could review the attached lecture and update this for Ortho Biotech. If you need administrative assistance with this, please contact me at \_\_\_\_\_ Phone \_\_\_\_\_.

The training school is being held at \_\_\_\_\_. I will contact your office to arrange car service for you to conference center the day of your talk.

The honorarium for this talk is \$1,000.00 along with reimbursement for revisions made on the lecture. Please sign this letter as confirmation of your agreement to present this lecture.

Thank you again for taking time out of your busy schedule to present at this training school. If you have any questions, please feel free to contact me at \_\_\_\_\_ Phone \_\_\_\_\_.

Sincerely,

\_\_\_\_\_  
(Administrative Associate)

Agreed and accepted:

\_\_\_\_\_  
(HCP Signature)

Please forward copies to each of the following:

- 1) The Consultant (HCP)
- 2) The HCC Department
- 3) Originator of agreement

**CLERKSHIP CONFIRMATION LETTER**

Health Care Professional (HCP)  
(Addressee)

Dear HCP:

Thank you for agreeing to allow me to visit your office on (DATE). The purpose of this visit is educational in nature, not to sell PROCRIT® or any other Ortho Biotech, Inc. products. Specifically, I want to expand my knowledge of the types of patients in your practice.

The honorarium for assisting in this phase of my education is \$250/\$500. I have attached a copy of the OBI Clerkship Guidelines that I have been instructed to follow.

Please sign this letter as confirmation of your agreement to allow me to attend this clerkship.

I look forward to this educational experience and will see you on (DATE).

Sincerely,

Product Specialist

Signature and Date

Agreed and Accepted:

(HCP Signature and Date)

Please forward copies to each of the following:

1. The Sales Training Department
2. The Consultant
3. The HCC Department
4. Originator of agreement

## CLERKSHIP/PRECEPTORSHIP GUIDELINES FOR PRODUCT SPECIALISTS

When attending a clerkship or preceptorship with a healthcare professional (HCP), the Product Specialist (PS) must adhere to the following guidelines listed below:

- All patient information shared with the PS is confidential and should be treated as such.
- All OBI product inquiries from patients should be referred to the HCP, not the PS. The PS cannot respond directly to product inquiries from patients.
- PS's must not accept any confidential information regarding trade secrets within the practice/institution.

This document must accompany a signed confirmation letter to the physician or institution.

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700 U.S. Highway 202  
P.O. Box 670  
Raritan, NJ 08869-0670

**DRAFT**

**CONSULTING AGREEMENT**

AGREEMENT made this [Day] of [Mo./Yr] between [Name] (the "Consultant"), a resident of [State/Country], and Ortho Biotech Inc. (the "Company"), a New Jersey corporation.

**Preliminary Statement**

Consultant represents that he is under no obligation to any third party that would interfere with his rendering to the Company the professional services described in and covered by this Agreement. The Company has now and from time to time in the future may have the desire to engage Consultant's professional services. Consultant desires to render professional services to the Company on a non-exclusive basis in the provision of training and other matters described in this Agreement. Consultant is uniquely qualified to provide advice and counseling concerning the matters set forth in Exhibits to this Agreement and related services because of the Consultant's professional training, experience and reputation.

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the parties hereto agree as follows:

- 1) This agreement covers a period of [enter duration of agreement, typically 1-3 years] from the date of execution during which Consultant shall perform the services set forth in Exhibit A.
- 2) Consultant shall provide consulting services in accordance with the terms hereof, keep the Company advised of the progress of the work, provide the Company with such reports as are appropriate to the nature of the services and keep records of hours worked as well as other reasonable out-of-pocket expenses, which records a duly authorized representative of the Company may examine.
- 3) As part of this agreement and for a period of five (5) years from termination, any confidential information acquired by Consultant from the Company or provided by Consultant to the Company including but not limited to confidential information concerning existing or contemplated products, processes, techniques, or know-how, or any proprietary or confidential information or data developed pursuant to the performance of the consulting services contemplated hereunder shall not be disclosed by Consultant to others or used for Consultant's own benefit without written consent of the Company. The foregoing obligation shall not apply to any confidential information which: (i) without fault of the receiving party becomes a part of the public domain; or (ii) is disclosed to the receiving party by a third party with the right to disclose it and without further restrictions on disclosure by the receiving party. It is understood by the parties that Consultant possesses unique expertise in the subject matter of this Agreement. Consultant will use and rely upon its extensive prior knowledge and expertise but cannot and will not use or disclose proprietary or confidential information it may possess, if any, from any other source.

4)

- a) Any inventions, improvements, or ideas made or conceived by Consultant in connection with or during the performance of services contemplated hereunder, which result in a scientific improvement to any product distributed by or which is the subject of research and/or development by or for the Company shall be the property of the Company. At the Company's request, Consultant shall execute, acknowledge, and deliver to the Company all such further papers, including applications for patents, as may be necessary to enable the Company to publish or protect said inventions, improvements, and ideas by patent or otherwise in any and all countries and to vest title to said patents inventions, improvements, and ideas in the Company, or its nominees, their successors or assigns, and shall render all such assistance as may require in any patent Office proceeding or litigation involving said inventions, improvements, or ideas.
  - b) Any copyrightable work created by Consultant in connection with or during the performance of services contemplated hereunder shall be considered a work made for hire, whether published or unpublished, and all rights therein shall be the property of the Company as employer, author and owner of copyright in such work.
- 5) Both parties reserve the right to discontinue, at any time, any work authorized by this Agreement, provided however, the Company shall be obligated to pay Consultant only for work done by Consultant. Upon termination, Consultant shall promptly return any materials and copies thereof provided by the Company or reflecting confidential information to the company. After termination, Consultant, without charge to the Company other than reasonable payment for time involved shall, in accordance with paragraph 4, duly execute, acknowledge, and deliver to the Company all such further papers, including assignments and applications as may be necessary to enable the Company to patent, publish copyright or protect said works in any and all countries and to vest title to said works in the Company or its nominees, their successors or assigns, and shall render all such assistance as the Company may require in any proceeding or litigation involving the rights in said works.
- 6) Subject to prior written notice to Consultant, the Company shall have the right to list Consultant in its promotional literature as a consultant, along with any pertinent information relating to professional credentials of Consultant.
- 7) In consideration of its acceptance of this Consulting Agreement and of its performance of the professional services as specifically set forth in paragraph 1 hereof, the Company shall pay Consultant in accordance with Exhibit B.
- 8) It is expressly stipulated, agreed and understood between the parties that the relationship between Consultant and the Company shall be that of independent contractor and not employer-employee or principal-agent. Neither party shall have the authority to legally bind the other in contract, debt, or otherwise.
- 9) Any notice required shall be by mailing of any letter or instrument by registered mail, return receipt requested, postage pre-paid by the sender or by personal delivery to a representative of the Company.

If to Consultant, to:

[Name/address]

If to the Company, copies to:

[1. OBI contact person & address, if applicable and 2. OBI board position listed by title rather than name (e.g. Vice President, Corporate Development & address)]

- 10) This Agreement contains the complete understanding between the parties and as of the date hereof, supersedes all other agreements, whether they are written or oral, between the parties.
- 11) No waiver or modification of this Agreement or any covenant, condition or limitation herein contained shall be valid unless such waiver or modification is in writing duly signed by both parties.
- 12) All agreements and covenants contained herein are severable and in the event that any of them shall be held to be invalid by any competent court, this Agreement shall be interpreted as if such invalid agreement or covenant is not contained herein.
- 13) This Agreement shall be binding on and inure to the benefit of each party, its successors or assigns, subsidiaries, affiliates or transferees.
- 14) This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey.

IN WITNESS WHEREOF the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

Consultant

By \_\_\_\_\_  
[Name]

Ortho Biotech Inc.

By \_\_\_\_\_  
[Director or above]

## **EXHIBIT A**

[NOTE: If needed, exhibits C, D, etc. can be added to describe different consulting projects within the overall term limit of the agreement]

*Company Contact:*

[List the primary OBI contact person here including relevant phone, email, address, etc.]

*Qualifications of Consultant:*

[Briefly describe qualifications of the consultant to perform the services described below. This can be paraphrased from a recent version of the consultant's CV.]

*Description of consulting services:*

[Briefly outline the services you expect from the consultant. Be as specific as possible to avoid misunderstanding or confusion (e.g. provide advice in person and on telephone on Y subject, review information and write a report on X subject, be available for four (4) annual advisory board meetings, etc.).]

*Term of work:*

[Enter completion date(s) here. If necessary, interim delivery or review dates can also be included] Any work beyond this date requires written authorization to proceed from the Company.

**EXHIBIT B**

In exchange for consulting services described in the attached document, the Company agrees to compensate the Consultant as follows:

- 1.) [List consulting fees here – must not exceed fair market value consistent with rates for services rendered]
- 2.) Reimbursement for pre-approved expenses incurred as a part of consulting services in compliance with Ortho Biotech Inc. travel and reimbursement guidelines.

The Consultant will provide a monthly invoice to the Company. The invoice should include a description of services provided, number of hours (or days) worked and expenses submitted for reimbursement.

Invoices should only be paid upon actual services performed. Pre-payments and signing bonuses are normally not appropriate. Contact HCC for exceptions.

*Product Specialists are required to review the HCC guidelines on reverse side of this form prior to submission*

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**ORTHO BIOTECH**

**rev a1.2**

**CLERKSHIP REQUEST FORM**

**Critical Care/Surgery** \_\_\_\_\_ **Immunology** \_\_\_\_\_ **Nephrology** \_\_\_\_\_ **Oncology** \_\_\_\_\_

(please select franchise)

**Region/District Name:** \_\_\_\_\_ **RDT #:** \_\_\_\_\_

**Product Specialist Name:** \_\_\_\_\_ **VoiceMail #:** \_\_\_\_\_

**Amount (please select amount):** \_\_\_\_\_ **Payable To:** \_\_\_\_\_

**Physician \$500:** \_\_\_\_\_

**Other \$250:** \_\_\_\_\_

**Tax ID #:** \_\_\_\_\_ **Send Check To:** \_\_\_\_\_

**or**

**SS #:** \_\_\_\_\_

**Name of Contact Person at Institution:** \_\_\_\_\_

**Contact's Phone Number:** \_\_\_\_\_

**Detailed description of initiative to be funded:**

\_\_\_\_\_

**Product Specialist Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**DM Approval Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Dir. Sales Training Approval Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
(for amounts greater than \$500.00, DM must fax to Dir. Sales Training @ 908-575-0074 for approval)

**Product Specialists please complete and fax form along with "Confirmation Letter" to your DM Office for Approval**  
**District Managers please review, approve and fax to MarketChek @ 718-863-3445 for processing**

**District Managers must also fax "Confirmation Letter" to MarketChek for check to be issued**

Please visit [www.marketcheck.com](http://www.marketcheck.com) for order status, or call us @ 718-821-4820

**Health Care Compliance Clerkship Guidelines – rev b1.2**

When attending a clerkship with a healthcare professional (HCP), the Product Specialist (PS) **MUST ADHERE** to the following guidelines listed below:

- All patient information shared with the PS is confidential and should be treated as such.
- All OBI product inquires from the patient should be referred to the HCP, not the PS.  
The PS cannot respond directly to product inquires from patients.
- PS's must not accept any confidential information regarding trade secrets within the practice/institution

The "Clerkship Request Form" and the signed "Confirmation Letter" must be faxed to your DM for the Clerkship to be processed.

DM must fax both the "Clerkship Request Form" and the signed "Confirmation Letter" to MarketChek for the check to be issued. (for amounts greater than \$500.00, DM must fax to Dir. Sales Training @ 908-575-0074 for approval)

"Confirmation Letter" templates are available from the Sales Training Department on the OBI Net.

*If you have further questions, please review "OBI Best Practices Guidelines" or contact your DM or RBD*

Consulting and Services  
Provided to Customers  
Section 2

# ORTHO BIOTECH

## Consulting and Services Provided to Customers

### Overview

When considering providing a program/service to a customer or health care professional, you must first determine if the program/service is product related and value added. Limited types of product related, value added services may be offered to customers or health care providers for free. Other types of value added services are sold to customers by companies like the Johnson & Johnson Consulting Group. For a definition of value-added programs, please refer to the glossary.

Examples of OBI product related value added programs include:

- Oncology Nurse Educators/AIDS Educators/Other nurse educators.

### Policy and OBI Procedures

Value added programs/services that may be offered for free to customers must meet the following criteria:

- Closely related to OBI products
- Offered to all customers free of charge
- Not normally performed by the customer's employees or purchased by the customer on the open market
- Are within OBI normal sales & marketing overhead

Nurse Educators meet these requirements as long as they provide educational services to all customers. This would include in-service presentations, patient support groups, and education on appropriate patient selection, etc.

OBI may not pay the customer's costs for services furnished by an outside consultant. OBI may not provide or perform services for free that healthcare professionals would normally pay for to enhance or sustain their business or otherwise offset their overhead. If the services are outside the guidelines for "free" value added services, you must obtain a written agreement appropriate for a specific situation. Contact the HCC Department for approval before entering into an agreement.

See Consulting and Services Provided to Customers process flow in Section 2-4.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.***

### OBI Related Documents, Templates and Forms

Not applicable

**Questions and Answers**

**Q1:** May OBI offer free consulting services from D. J. Sullivan (JJHCS Hospital Management Consultant)?

**A1:** No. D. J. Sullivan services are not considered value-added programs since they are not normally provided to all healthcare professionals without a charge. If such services were made available to a customer along with the sale of product, this would be considered a combined products and services arrangement. This would require a signed agreement (Contact HCC Dept.).

**Q2:** Is it permissible for OBI to provide a media campaign (produce television spots, announcements, etc.) to a single customer in exchange for the customer's promise to purchase a certain amount of OBI's product?

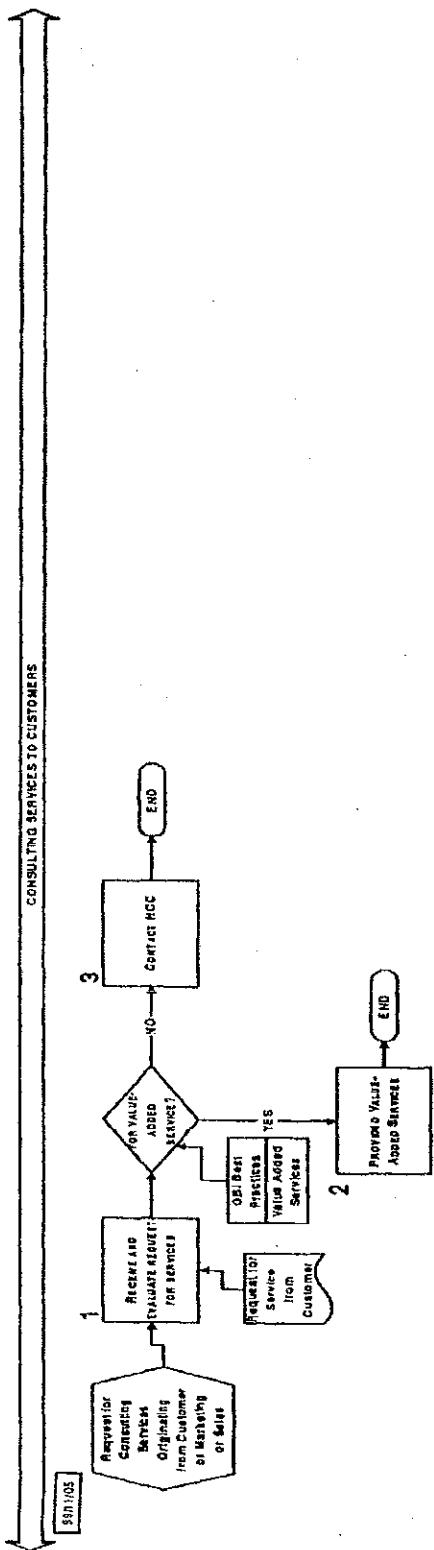
**A2:** Not as proposed. Generally, value-added services may not be offered to a select customer or customers, especially if OBI sells the services to customers, or if the services are of the type that would be purchased by the customer on the open market. Furthermore, a J&J operating company may not offer services in exchange for the customer's promise to purchase a certain amount of company product. It is permissible, however, for OBI to share in the cost of a media campaign with a customer provided that OBI's financial contribution to the campaign represents fair market value for the advertising it receives.

**Q3:** Am I able to pay for an outside vendor to help with training my customer on computer software?

**A3:** No. The only exception would be if the software were product related. In addition, it would have to be made available free of charge to all OBI customers.

**More Information**

- Educational Grants/Research Grants/Speakers Programs Guideline #3



## Consulting to Customers Key Process Steps

- 1 - Evaluate consulting request from a customer
- 2 - If the services can be offered as "value-added" according to the guidelines then offer services
- 3 - If the services cannot be offered as "value-added" services then contact HCC.

Educational Grant/Research  
Grants/Speaker Programs  
Section 3

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# ORTHO BIOTECH

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- Speakers Programs ..... Page 3-10
- Customer-Initiated Clinical Research Grants ..... Page 3-26
- Customer-Initiated Preclinical or In-Vitro Research Grants ..... Page 3-30

# ORTHO BIOTECH

## Educational Grants

### Overview

Ortho Biotech recognizes that providing Educational Grants is an important part of conducting business. Grants are available in several forms, each with specific regulations. Educational grants to OBI healthcare professionals and customer organizations are subject to limitations and may not be contingent upon the use of products.

### Policy and OBI Procedures

An independent educational project is one in which the content is not promotional and is not controlled or influenced by OBI. This can include symposia, Continuing Medical Education (CME) programs, publications, grand rounds, and support of third party educational materials. The purpose of the program must be educational and OBI must be "hands off" with respect to approving the content of the program or speakers. These programs should foster scientific, clinical and/or patient education in areas of interest to the company. All grants must sponsor a specific event. There is no such thing as an "unrestricted educational grant" to a customer.

#### Educational grants must:

- Support specific bona fide educational initiatives for customers or patients
- Have a clearly defined purpose; **unrestricted educational grants are not valid**
- Initiatives must be related to disease states of interest to OBI
- Be provided without condition of product use
- Not be used for normal organizational overhead
- Not support initiatives that are part of an organization's normal operation and responsibilities
- Not be provided to an individual

Educational Grants may be produced for the development or dissemination of provider/patient education materials. The following criteria must be met:

- OBI must receive the right to use the materials developed
- The amount of the grant must be limited to items specifically identified in a customer prepared budget and consistent with the fair market value of those items

Awards may be given in certain circumstances. Awards should in no way benefit an OBI product or result in formulary preference, increased prescription volume, etc. The recipient of any award must be selected by a panel of non-OBI employees with no knowledge/dependency on whether the customer prescribes or can influence sales of our products. All award programs must be submitted to Product Management and the Health Care Compliance Department for approval.

Fellowships grants may offer support to teaching institutions for their medical education programs by sponsoring fellows. Fellowship grants must:

- be provided to the institution rather than individuals, selection of the grant recipient must not be controlled by Ortho Biotech
- be provided without condition of product use

Research is supported through the Clinical Affairs Department. Consulting agreements must be in place for any research arrangement. Please refer any requests for research funding to the Clinical Affairs Department. (See section Arrangements to Obtain Consulting and Other Services from Customers Guideline #1)

Each grant request requires management approval and supporting documentation. Generally payments are made to institutions, not individuals.

See Educational Grants process flows in Section 3-6.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

**OBI Related Documents, Template and Forms**

- Educational Grant Checklist
- Grant request form

**Questions and Answers**

**Q1:** A Product Specialist conducting a speakers program at a local restaurant wants to cover the dinner expenses as a grant. Is this allowable?

**A1:** No. The meals portion of the program is considered entertainment and is handled through normal expense reporting.

**Q2:** A hospital is sponsoring a fund raiser for their breast cancer support network, a non profit, tax exempt organization. Can this be supported with a grant?

**A2:** No. This must be handled as a charitable contribution provided it meets all the requirements outlined.

**Q3:** Can a grant be provided to a Chief Resident to sponsor a boating event to welcome all new residents to the hospital?

**A3:** No. This type of program cannot be supported through an educational grant because it is not for a bona fide educational initiative. Modest social events are permitted under some circumstances as an entertainment expense.

**Q4:** A large Physician Management group would like to develop patient education materials for symptom management or a newsletter on anemia. Can OBI support this initiative?

**A4:** Yes. Provided that all requirements for development or dissemination of educational materials are met, the support is reasonable in relation to the cost of producing the materials, and OBI obtains the rights to use these materials. If the educational material contains information on OBI products, a written agreement must stipulate that the information is consistent with approved product labeling.

**Q5:** Can we provide funds for two nurses at a major hospital to travel to, and attend, ASCO?

**A5:** Yes. Provided the hospital selects which nurses attend ASCO, with no influence by OBI; and all other grant requirements are met.

**Q6:** Can OBI provide a grant to support a physician's or hospital's holiday party?

**A6:** No. This is not an educational program and grants may only be used to support bona-fide educational programs.

**Q7:** Can OBI give an educational grant to support a national managed care organization's annual meeting of medical directors?

**A7:** No. Grants may not be provided to support routine customer business meetings. However, limited assistance may be given to fund the actual direct costs of an educational speaker (i.e., honorarium, handouts) at the meeting.

**Q8:** May OBI pay a physician to present a luncheon speech on a new OBI indication?

**A8:** Yes. But this does not qualify as a Grant. There must be a written agreement with the speaker to ensure that his/her remarks remain within product labeling. This information which must be available to attendees. In addition, the amount of the payment must be consistent with fair market value (See Speaker Programs Section #3).

**Q9:** I am a Sales Manager who would like to have a Physician conduct a training session (Preceptorship) for local medical professionals and my staff on the proper use of PROCRIT®. Can I provide a Grant for this purpose?

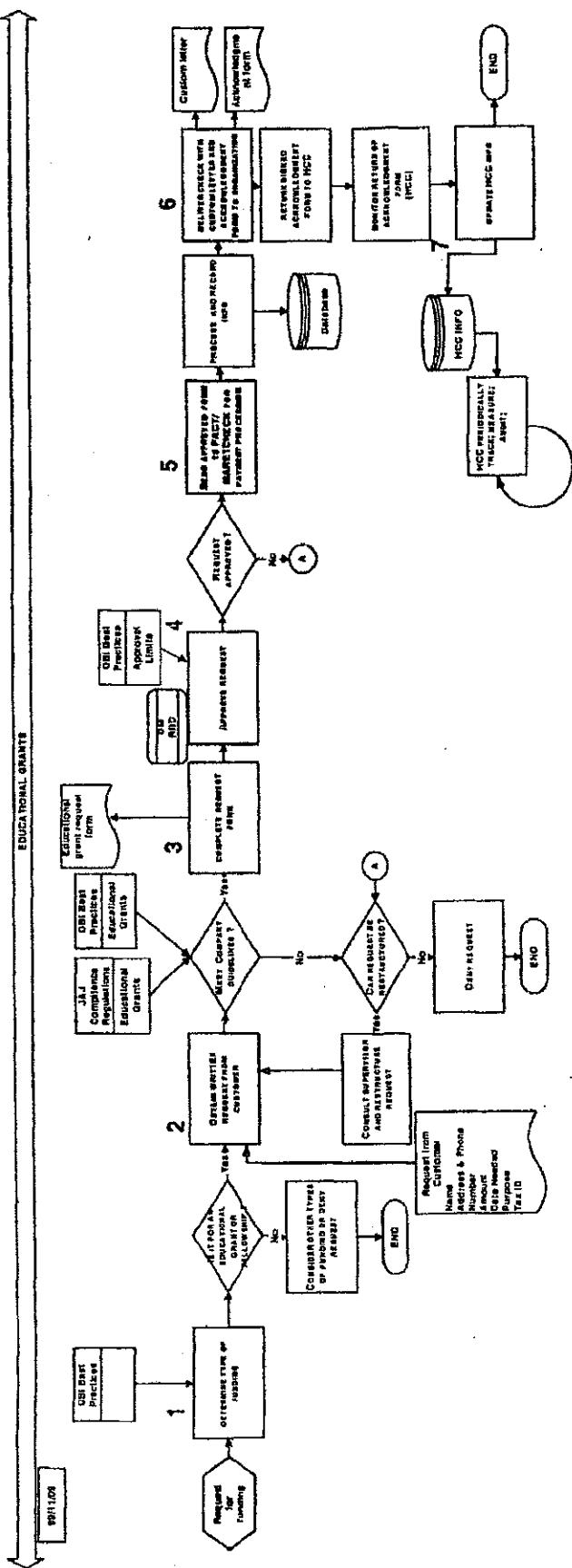
**A9:** Preceptorships are not eligible for grants. This is a situation where we are hiring a customer to speak on our product, and as such, must comply with the HCC policy on Arrangements to Obtain Consulting and Other Service from Customers Section #1.

**Q10:** Why can we no longer do "unrestricted grants"?

**A10:** There is no such thing as an unrestricted educational grant. All educational grants are for some purpose. If supplied as an "unrestricted" grant, it may be viewed as an inappropriate inducement, or as hidden discounts. Therefore, it is in the best interest of OBI and the customer to clearly state the purpose for which the grant is given.

#### **More Information**

- Arrangements to Obtain Consulting and Other Services from Customers Guideline #1
- Charitable Contributions Guideline #17



## Educational Grants Key Process Steps

- 1 - Determine if the funding fits guidelines for educational grants
- 2 - Obtain written request from the customer
- 3 - Fill out the request form
- 4 - Obtain approval - <\$3000 - DM; >\$3000 - RBD
- 5 - Process and record information through PACT/Marketcheck
- 6 - Deliver check with custom letter and acknowledgment forms
- 7 - Submit documentation to HCC

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**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

**EDUCATIONAL GRANT CHECKLIST**

	<u>YES</u>	<u>NO</u>
Does the request support bona fide educational initiatives?		
Is the initiative clearly specified in the request?		
Is the initiative related to a disease state of interest to OBI?		
Is the grant provided without condition of product use, formulary status, or purchasing commitment?		
Is the grant recipient an organization rather than an individual?		
Does the grant preclude the use for normal overhead of the organization?		
Does the grant preclude the use for initiatives that should be part of the recipient's normal operation and responsibilities?		
If the grant is to support the development or dissemination of provider/patient education materials: <ul style="list-style-type: none"> <li>– Will OBI receive the right to use materials developed?</li> <li>– Will the amount of the grant be limited to items specifically identified in a customer prepared budget and consistent with the fair market value of those items</li> </ul>		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT OR CONSULT WITH THE HCC DEPARTMENT.**

# ORTHO BIOTECH

## SPEAKER PROGRAMS

### Overview

Support for speakers generally fall into three areas:

1. Promotional speaker programs which present information on OBI products consistent with approved package labeling.
2. Customer sponsored educational programs.
3. Independent Educational CME SpeakerPrograms where OBI does not control the content of the presentations. Content is controlled by a third party.

### Policy and OBI Procedure

#### Promotional Speaker Program

These programs are those where OBI controls or influences content and/or selection of speakers. They are promotional in nature. They are generally handled through a speakers program vendor and programs must comply with the following:

- Information presented must be within approved product labeling and fairly balanced.
- Handouts or other visual aids must be prior approved through the OBI Approval Committee.
- Full prescribing information must be available to attendees.
- Written agreement with the speaker must be in place (see template).
- Any gifts/remuneration's to attendees must be limited to modest value, nominal value items (i.e., mugs, pens, pads) and/or a patient care related item of modest value, consistent with the Entertainment and Gifts guideline section #10.

A company representative may be present and engage in promotional discussions of products. Sales materials and literature may be disseminated at these programs (as long as they meet the above criteria).

#### Educational Programs with Customers

In many cases, customers request educational grants from us to support educational speakers or activities. OBI may provide support for specific bona-fide educational functions. The programs must comply with the following:

- Support for the program may not be contingent upon any commitment to purchase, use, or recommend OBI products.
- OBI support must be limited to specific educational program costs identified in a customer prepared budget and may not be used to pay for a customer's general conference overhead as those expenses are considered to be part of their ordinary business expense.

- Information presented on OBI products must remain within FDA approved product labeling.
- A written agreement with the customer must be in place that requires OBI's sponsorship of the program, and any significant financial relationship with the speaker must be disclosed. The agreement must also require that the customer will ensure that the speaker remains within product labeling when discussing OBI products.
- OBI may sponsor modest social events in connection with the CME program as long as the activity does not interfere with or distract from the educational program.

#### **Independent Educational CME Speaker Programs**

An Independent Educational CME Speaker Program is one in which the content is non-promotional and is not controlled or influenced by OBI. OBI must be "hands off" with respect to influencing the content and selection of speakers.

OBI support must be consistent with the FDA's Guidance on Industry Supported Scientific and Educational Activities and the ACCME Standards for Commercial Support of Continuing Medical Education.

These programs are conducted by an independent (non-customer) accredited CME provider. OBI may provide an educational grant to support these programs and may limit their support to topics of interest to the company. OBI may discuss potential topics but the CME provider must maintain control over the specific content and must commit to providing a balanced presentation of information. Upon request of the CME provider, OBI may suggest speakers as long as more than one speaker is present. All CME programs must be approved by the J&J Law Department, namely Regulatory Counsel, for compliance with FDA regulations. These programs must comply with the following:

- OBI's support of the program and any significant financial relationships with the speaker must be disclosed to the audience. If any off label uses are mentioned, the lack of FDA approval must be disclosed.
- Written agreement must be in place with the CME provider requiring the above and specifying that the program sponsor, and not OBI, is responsible for the content.
- OBI may not prepare scripts but may provide technical assistance with the production of slides to the speaker based on information furnished by the speaker.
- No OBI exhibits are permitted near the presentation area.
- OBI may sponsor modest social events in connection with the CME program as long as the activity does not interfere with, or distract from, the educational program.
- OBI may not pay for attendees' registration fees or expenses in connection with attending the program.
- OBI personnel may be present, but may not engage, in any promotional activity (i.e., detailing of products, dissemination of articles, or materials of any nature).

See Speaker Programs process flows in Section 3-14.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

**OBI Related Documents, Template and Forms**

- Visiting Faculty/Speaker Agreement
- Educational Speakers Program with Customers Checklist

**Questions and Answers**

**Q1:** A product specialist has already arranged for an upcoming speaker program. Does that product specialist need to have that speaker sign an agreement to remain on-label?

**A1:** No. The marketing department of each franchise will arrange to have agreements signed by all speakers through our Visiting Faculty Program. It will also become standard procedure for the Visiting Faculty Program vendor to ensure that all speakers have a signed contract on file prior to their speaking on our behalf.

**Q2:** A customer requests a specific speaker to speak on a topic that is off-label. You will not be controlling the content of the talk. Can you sponsor this speaker?

**A2:** No. Any program you support through Ortho Biotech Visiting Faculty/Speakers Bureau, is considered a promotional speakers program. If the presentation is off-label, you may not sponsor the program as a promotional speakers program.

**Q3:** Can I be present at an Ortho Biotech sponsored CME program?

**A3:** Yes. You may be present. However, CME programs are independent educational programs and under CME guidelines, you may not conduct any promotional activities. You should not wear an OBI name tag and may not promote OBI products in any way, (i.e., displaying literature, handing out pens, or discussing use of our products with attendees).

**Q4:** My institutional account is a CME provider and would like to put on a CME program. They have asked for my support. Can I do this?

**A4:** Yes. All sponsorship of CME programs requires a written agreement. If you encounter this situation, you should contact the marketing department for support.

**Q5:** Can OBI hire an outside speaker who is a government employee to speak at an internal meeting of salespeople to discuss reimbursement issues?

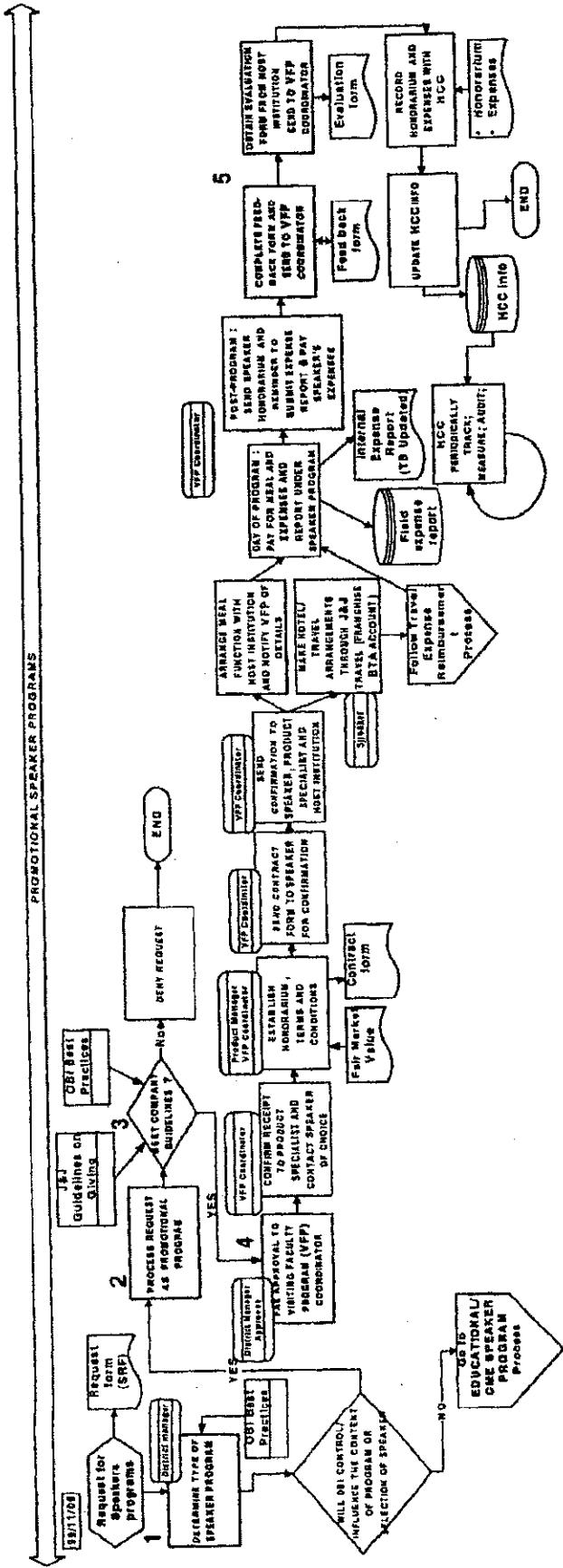
**A5:** No. If the speaker is a federal, state, or local government employee, OBI cannot provide any gifts, gratuities, or honoraria (including payment for travel costs or expenses) to the government speaker. This includes any physician, nurse, or other governmental health care professional. Limited exceptions may exist when certain government institutions allow its employees to participate. Consult the HCC Department. (See Guidance Document on Gratuities to Government Employees in Section #14).

**Q6:** Can OBI hire an independent consultant in the field of reimbursement, a physician, or a non-physician customer to speak at an internal OBI meeting of salespeople?

**A6:** Yes. Provided that the payment for the speaking engagement is consistent with fair market value for such an activity, there is a written agreement between the parties identifying the activities to be performed, the materials to be developed in connection with the speaking engagement, and the compensation to be paid for the engagement.

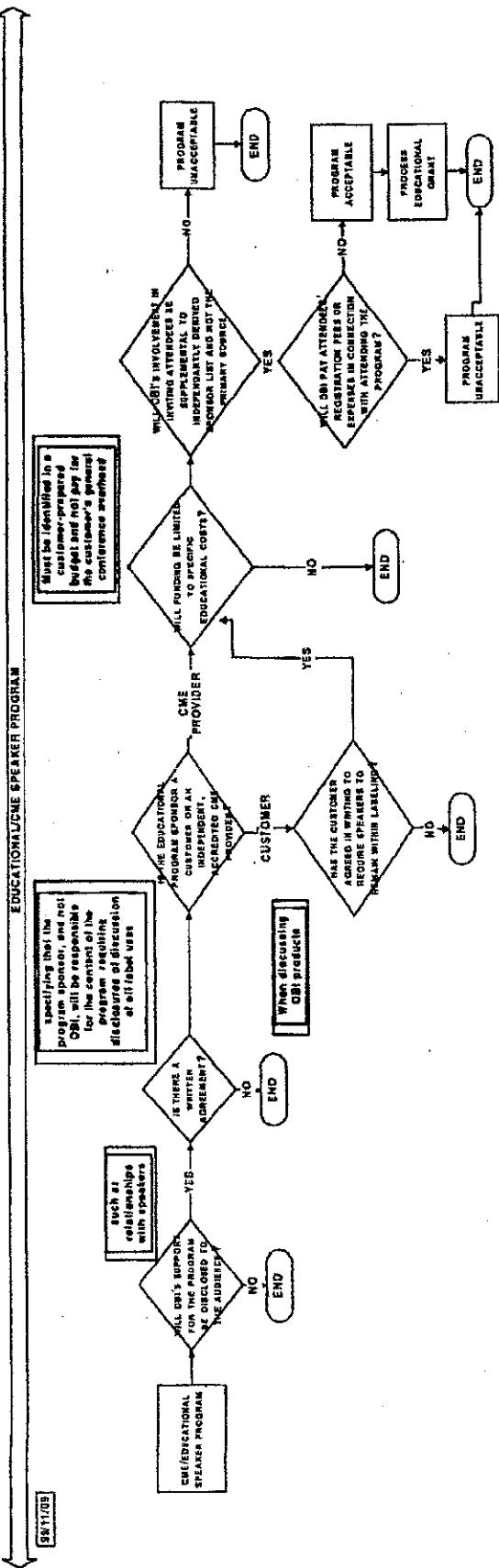
**More Information**

- Arrangements to Obtain Consulting and Other Services from Customers Guideline #1
- Travel and Expense Reimbursement Guideline #11



## Promotional Speaker Programs Key Process Steps

- 1- Determine if the program content or selection of speakers will be under the control/influence of OBI
- 2- Process request
- 3- Determine if the program content meets **GUIDELINES**
- 4- Obtain approval
- 5- Complete evaluation forms and return to the Visiting Faculty Program Coordinator



## Educational/Customer Sponsored Programs and CME Programs Key Process Steps

1. Ensure program is related to a disease state of interest to OBI
2. Obtain signed agreement from customer or CME provider
3. Provide educational grant to customer or CME provider

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**ORTHO BIOTECH**

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**OBI Related Documents, Templates and Forms**

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**ORTHO BIOTECH**

700 U.S. Highway 202  
P.O. Box 670  
Raritan, NJ 08869-0670

**DRAFT**

**VISITING FACULTY / SPEAKER AGREEMENT**

AGREEMENT made this [Day] of [Mo./Yr] between [Name] (the "Consultant"), a resident of [State/Country], and Ortho Biotech Inc. (the "Company"), a New Jersey corporation.

**Preliminary Statement**

Visiting Faculty member (also referred to as Speaker) represents that (s)he is under no obligation to any third party that would interfere with his/her rendering to the Company the professional services described in and covered by this Agreement. The Company has now and from time to time in the future may have the desire to engage Speaker's professional services. Speaker is uniquely qualified to provide training, lectures and other presentations concerning the matters set forth in Exhibits to this Agreement and related services because of the Speaker's professional training, experience and reputation.

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the parties hereto agree as follows:

- 1) This agreement covers a period of [enter duration of agreement, typically 1 year] from the date of execution during which Consultant shall perform the services set forth in Exhibit A.
- 2) Speaker shall provide services in accordance with the terms hereof, keep the Company advised of the progress of the work, provide the Company with such reports as are appropriate to the nature of the services and keep records of hours worked as well as other reasonable out-of-pocket expenses, which records a duly authorized representative of the Company may examine.
- 3) As part of this agreement and for a period of five (5) years from termination, any confidential information acquired by Speaker from the Company or provided by Speaker to the Company including but not limited to confidential information concerning existing or contemplated products, processes, techniques, or know-how, or any proprietary or confidential information or data developed pursuant to the performance of the services contemplated hereunder shall not be disclosed by speaker to others or used for speaker's own benefit without written consent of the Company. The foregoing obligation shall not apply to any confidential information which: (i) without fault of the receiving party becomes a part of the public domain; or (ii) is disclosed to the receiving party by a third party with the right to disclose it and without further restrictions on disclosure by the receiving party. It is understood by the parties that the speaker possesses expertise in the subject matter of this Agreement. Speaker will use and rely upon its extensive prior knowledge and expertise but cannot and will not use or disclose proprietary or confidential information it may possess, if any, from any other source.

4)

- a) Any inventions, improvements, or ideas made or conceived by Speaker in connection with or during the performance of services contemplated hereunder, which result in a scientific improvement to any product distributed by or which is the subject of research and/or development by or for the Company shall be the property of the Company. At the Company's request, Speaker shall execute, acknowledge, and deliver to the Company all such further papers, including applications for patents, as may be necessary to enable the Company to publish or protect said inventions, improvements, and ideas by patent or otherwise in any and all countries and to vest title to said patents inventions, improvements, and ideas in the Company, or its nominees, their successors or assigns, and shall render all such assistance as may require in any patent Office proceeding or litigation involving said inventions, improvements, or ideas.
  - b) Any copyrightable work created by Speaker in connection with or during the performance of services contemplated hereunder shall be considered a work made for hire, whether published or unpublished, and all rights therein shall be the property of the Company as employer, author and owner of copyright in such work.
- 5) Subject to prior written notice to Consultant, the Company shall have the right to list Speaker name as a Speaker, along with any pertinent information relating to professional credentials of Speaker.
- 6) In consideration of its acceptance of this Visiting Faculty Program Agreement and of its performance of the professional services as specifically set forth in paragraph 1 hereof, the Company shall pay Speaker in accordance with Exhibit B.
- 7) It is expressly stipulated, agreed and understood between the parties that the relationship between Speaker and the Company shall be that of independent contractor and not employer-employee or principal-agent. Neither party shall have the authority to legally bind the other in contract, debt, or otherwise.
- 8) This Agreement contains the complete understanding between the parties and as of the date hereof, supersedes all other agreements, whether they are written or oral, between the parties.
- 9) No waiver or modification of this Agreement or any covenant, condition or limitation herein

IN WITNESS WHEREOF the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

Speaker:

By \_\_\_\_\_  
[Name]

<Visiting Faculty Program Vendor>

By \_\_\_\_\_

## EXHIBIT A

### **Program Description**

The Ortho Biotech Distinguished Faculty Program is a national speakers program developed and implemented by Phase Five Communications Inc. This program is sponsored by Ortho Biotech Inc. in support of PROCRIT® (Epoetin Alfa). The curriculum for this program is sourced from the most recent clinical data.

### **Program Objectives**

The objective of the program is to present a comprehensive lecture on your topic. This includes clinical data, available therapeutic options and the role of PROCRIT.

The audience will consist of physicians, nurses, pharmacists, nurse practitioners, and other appropriate health care professionals.

### **Curriculum Topics**

The program topic preferences you indicated on your speaker profile form are part of our database. This information will be the basis of speaker selection in relation to specific requests.

The information that follows is intended to provide each faculty member with a complete understanding of program logistics.

### **Lecture Format**

- Lecture kit with slides and notes provided to each faculty member to augment the presentation
- No cost to host institution
- All program scheduling handled by Phase Five Communications Inc.

### **Role of <Visiting Faculty Vendor>**

To assist the faculty in presenting PROCRIT program lectures, Phase Five Communications Inc. will do the following:

#### **Services**

- Consult with faculty members regarding use of program resource materials, presentation techniques, travel plans, and honoraria
- Schedule sites for each planned session
- Coordinate scheduling of the faculty's speaking engagements with recruited hospitals
- Inform the faculty as soon as possible of the cancellation or rescheduling of a lecture
- Arrange and prepay all airfare and hotel expenses

By signing this contract, you agree to remain within package labeling when discussing the use of any OBI product as part of program placed through this Faculty Program.

**Materials**

- Lecture kit titled *"Anemia in HIV Infection"* consisting of slides and lecture notes
- Evaluation forms, distribution to the sponsoring organization and returned to Phase Five Communications Inc.

**Cancellation Policy**

Of a faculty member must cancel a lecture, the scheduling coordinator must be notified at least 3 weeks in advance of the confirmed date; in the event of a cancellation within 48 hours of a planned lecture, the host organization's contact person must also be notified.

Phase Five Communications Inc. will follow the same protocol should a host organization cancel a lecture.

[List the primary contact person here including relevant phone, email, address, etc.]

## EXHIBIT B

### Honoraria

Listed below is a definition of each type of speaking engagement and honoraria:

- A. One lecture with half-day travel: Session presented during the day or evening that requires no out-of-town stay and permits the faculty member to practice at least 2 hours during the day.  
\$750 honorarium  
\$25 expenses
- B. One lecture with full-day travel: Travel and presentation time that interrupts a full day or 2 half-days of practice.  
\$1,000 honorarium  
\$25 expenses
- C. Two lectures with full-day travel: Travel and presentation time that interrupts 1 ½ to 2 days of practice.  
\$2,000 honorarium  
\$100 expenses

### Travel

The program includes reimbursement for coach airfare only.

To facilitate prepayment and arrangement of all travel, we are able to offer services through TSG International, a travel agency based in New York City. At the time a lecture is scheduled, please call Sheryl Goldfeder at TSG International (toll-free number, 1-800-635-0283) and make all arrangements to and from the lecture.

We discourage using a private agent, as our agent has already secured discounted rates from the major airline carriers. If you feel you need to use a private agent, please notify your program manager in advance, to ensure you receive proper reimbursement.

**Availability**

Please list below any blocks of time during 1998/1999 on which you will be unavailable to participate in the lecture program.

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In consideration of the planning, scheduling and execution of the speakers bureau lectures, we understand and agree to operate within the guidelines described in this faculty agreement.

\_\_\_\_\_  
**Faculty Member** \_\_\_\_\_  
Date: \_\_\_\_\_

\_\_\_\_\_  
**Phase Five Communications Inc.** \_\_\_\_\_  
Date: \_\_\_\_\_

Please return one copy in the self-addressed, stamped envelope to:

**Wes Sparks**  
Phase Five Communications Inc  
114 Fifth Avenue, 9<sup>th</sup> Floor  
New York, NY 10011

**EDUCATIONAL SPEAKER PROGRAMS WITH CUSTOMERS**  
**CHECKLIST**

	<u>YES</u>	<u>NO</u>
Did OBI refrain from controlling or influencing the content or selection of speakers for the program, other than discussing the general topic of the program with the sponsor or providing a list of potential speakers at the request of the sponsor?		
Will OBI's sponsorship of the program and any significant financial relationships with the speakers be disclosed to the audience?		
Will OBI's sponsorship of the program be limited solely to identifiable costs attributable to educational programs (i.e., speaker fees, cost of handouts) and not include subsidies for a customer's overhead (i.e., room rental fees), social functions or travel expenses of attendees?		
Will OBI's sponsorship of social events be limited to modest value events that do not interfere or conflict with the educational program(s) to be provided?		
Is there written agreement with the customer specifying its control over the content of the program and agreement to require speakers to remain within product labeling when discussing OBI products?		
Is the educational support unrelated to any commitment to purchase, use or recommend OBI products, including any commitment to place OBI products on formulary?		

**IF THE ANSWER TO ANY OF THE ABOVE IS "NO", RESTRUCTURE TO COMPLY WITH  
GUIDELINES ON EDUCATIONAL PROGRAMS WITH CUSTOMERS.**

# ORTHO BIOTECH

## Customer-Initiated Clinical Research Grants

### Overview

Research grants in the form of funds and/or free goods are occasionally requested by healthcare professionals to support clinical studies of interest to them. These customer-initiated clinical (human) research studies must address legitimate OBI business interests, meet acceptable experimental design criteria, and provide valid statistical rationale as determined by OBI Clinical Affairs.

### Policy and OBI Procedures

All requests for clinical research studies must be reviewed by qualified OBI Clinical Affairs associates. No OBI employee other than a qualified OBI Clinical Affairs associate may approve customer research, or provide free goods or funding.

If legitimate interest is determined, Clinical Affairs will request a protocol, case report form(s), informed-consent document, and budget for review and comment. Following appropriate business, scientific, and financial review, the study may be funded (and/or free goods supplied) and a consulting agreement processed, based upon scope and budgetary requirements of the study.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

### OBI Related Documents, Templates and Forms

- Support for Clinical Research Checklist

### Questions and Answers

**Q1:** May a Marketing, Sales, or R&D associate authorize funds or free goods in conjunction with a research study that involves humans, without having Clinical Affairs review the study?

**A1:** No. Clinical Affairs must review all research studies.

**Q2:** Can OBI engage a physician at a VA hospital to perform clinical research?

**A2:** Yes. OBI may engage a physician at a VA hospital to perform clinical research, so long as the research agreement is made between the VA and OBI, the physician has the consent of the VA to conduct the research, and the research otherwise meets the requirements of the Educational Grants/Research Grants/Speaker Programs Guidelines.

**Q3:** Under what circumstances can OBI offer bonuses to researchers for clinical trials?

**A3:** OBI can offer bonuses to researchers under the following circumstances. First, the bonus amount, and criteria for earning a bonus, must be set forth in OBI's initial contract with CRO or the investigator. The criteria for bonuses must be related to benchmarks of performance standards that are above and beyond the duties required under the contract, so that there are no "duplicate" payments for the same services. For example, if a clinical trial is to be completed by a certain date pursuant to the contract, and this fact is reflected in the contract fee, a bonus may not be paid for completion of the trial by that date. Second, no "off contract" bonuses or gifts may be offered to CRO's or trial administrators, such as a gift certificate to an enrollment nurse if the nurse enrolls a targeted number of patients.

**More Information**

- Arrangements to obtain Consulting and Other Services From Customers Best Practice Guideline #1

**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

**SUPPORT FOR CLINICAL RESEARCH CHEKLIST**

	<u>YES</u>	<u>NO</u>
Does the program involve clinical research?		
Has clinical affairs been consulted?		
Has a written consulting agreement been drafted and signed?		

**ALL CLINICAL RESEARCH IS THE RESPONSIBILITY OF THE CLINICAL AFFAIRS DEPARTMENT  
AND MUST BE CONDUCTED IN CONNECTION WITH A CONSULTING AGREEMENT.**

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# ORTHO BIOTECH

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## Customer-Initiated Preclinical or In Vitro Research Grants

### Overview

Customers may request research grants in the form of funds and/or free goods to support preclinical studies of interest to them. Policy regarding customer-initiated preclinical (animal) or in vitro (lab bench) research grants states that these requests must represent a legitimate business interest to OBI and meet acceptable experimental design criteria as determined by a Surgical R&D scientist and Clinical Affairs.

### Policy and OBI Procedures

Not applicable

*NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.*

### OBI Related Documents, Templates and Forms

Not applicable

### Questions and Answers

Not applicable

### More Information

Not applicable

Computer Hardware Software  
Section 4

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# ORTHO BIOTECH

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## Computer Hardware and Software

### Overview

This section addresses Ortho Biotech's policy and procedures on providing computer hardware and/or software to healthcare professionals.

### Policy and OBI Procedures

Ortho Biotech employees may not provide free computer hardware or software or similar office equipment as an inducement to use our products or services or as a "hidden" discount on those products or services.

Except in limited circumstances, OBI may not provide computer hardware or similar equipment (e.g. computers, monitors, printers, and fax machines) to healthcare professionals. Similarly, value-added (free) software may only be furnished to healthcare professionals in limited circumstance. Such arrangements should reflect customary restrictions to protect the company from equipment diversion, warranty claims, and the like. Here are some examples of "limited circumstances":

- **Integrated Hardware Product:** Computer hardware may be provided to the extent that it is physically and operationally integrated into a company product or system. It must be necessary to the operation of the product or system and is ordinarily offered for sale as part of that product or system without a separate charge.
- **Research arrangements:** Computer hardware may be provided as part of support for a bona fide research project consistent with the guidelines and included in a Consulting and Service Agreement.
- **Sale or lease:** Customers may purchase or lease computer hardware from J&J at fair market value.
- **Software sale or lease:** Computer software may be licensed to healthcare professionals for an appropriate license fee consistent with fair market value. Such arrangements should be documented in an appropriate licensing arrangement.
- **Value-added (free) software:** Value-added software may only be provided to a customer if (1) no provision is conditioned on or tied to the volume or value of J&J products or services purchased; (2) be of modest value; (3) software must be health care-related with primarily patient benefit; and (4) must have the purpose of integration into a J&J product or service, research program support, contain medical education materials, or relates to ordering or inventory management of J&J products.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

### OBI Related Documents, Template and Forms

- Checklist for Free Hardware and Software arrangements.

**Questions and Answers**

**Q1:** Can OBI provide a free fax machine to an oncology office for transmitting prescriptions?

**A1:** No. A free fax machine would not meet the standards in the Guidance Documents.

**Q2:** OBI provides a computer or other equipment to a hospital under a research agreement to conduct a Phase III clinical trial. Once the study is complete, may the hospital keep the computers?

**A2:** Yes. Provided the research agreement complies with the Guidance Document on Arrangements to Obtain Consulting and Other Services from Customers Guideline Section #1 and is part of fair market value compensation and is identified in the Agreement.

**Q3:** May I provide my physicians, managed care plans, or other customers with free medical education software on CD-ROM?

**A3:** Yes. As long as the software has been through OBI's Promotional Review Committee process and complies with the Entertainment and Gifts Guideline Section #10.

**Q4:** OBI develops decision support software to guide physicians in intervening with anemic patients during cancer treatment. Can this software be given free of charge to customers?

**A4:** Yes. Provided that this software, related to the use of an OBI product, does not have alternative business uses or more than a modest value on the open market, in addition it must be available to all customers.

**Q5:** An influential managed care plan is developing their proprietary web site on the Internet and has offered OBI the opportunity to fund the development and shape the content of the pages relating to Oncology. Can we pay for this project?

**A5:** At this time, it may be possible for us to provide links to an existing website or fund the product specific or disease state specific content for the website, pursuant to the guideline on Educational Grants. For further information contact the HCC Department.

**More Information**

- Arrangement to Obtain Consulting and Other Services from Customers Guideline #1

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**ORTHO BIOTECH**

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**OBI Related Documents, Templates and Forms**

**Checklist for Free Hardware and Software Arrangements**

**Hardware**

	<b>YES</b>	<b>NO</b>
Will the customer pay fair market value for the hardware?		
Is the hardware integrated into a J&J product?		
Is the hardware provided as part of support for a research project?		

**Software**

Will the customer pay fair market value for the software?		
Is the software integrated into a J&J product?		
Is the software provided as part of support for a research project?		
Is the software of modest value, not provided as a condition to purchases or recommendations of J&J products, patient-care related and not simply business software, and related to medical education or inventory management for J&J products?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT OR CONSULT WITH THE HCC DEPARTMENT.**



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# ORTHO BIOTECH

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## Training Programs

### Overview

Training programs must relate to the appropriate use of Johnson & Johnson [J&J] medical devices, and must be conducted in accordance with the Food and Drug Administration [FDA] approved labeling of such products or services. Training programs for pharmaceutical products are not permitted.

### Policy and OBI Procedures

OBI does not provide training programs for customers on medical devices.

*NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.*

### OBI Related Documents, Template and Forms

- Checklist for Training Programs

### Questions and Answers:

Not applicable

### More Information:

- Consulting and Services Provided to Customers Guideline #2
- Educational and Research Grants Guideline #3
- Entertainment and Gifts Guideline #10
- Travel Expense Reimbursement Guideline #11

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**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

**Checklist for Training Programs**

*(Devices and Equipment only)*

	Yes	No
Will the training program be limited to the FDA approved uses of J&J products?		
Is the training necessary to provide protection to J&J companies against potential product liability and related claims?		
Will the training program be provided at a J&J training center or in a clinical setting in which a device is ordinarily used?		
Will reimbursement of attendees be limited to the reasonable documented travel expenses?		
Can the training only be effectively provided through an "in person" program?		
Is there a written agreement with a trainer consistent with the requirements of the Guidance Documents on Consulting and Service Agreements?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT TO COMPLY WITH THE GUIDELINES OR CONSULT THE HCC DEPARTMENT BEFORE PROCEEDING.**

Commercial Sales Financing  
and Leases Section 6

# ORTHO BIOTECH

## Overview

Where Johnson & Johnson [J&J] companies are selling products or services directly to a customer, sales contracts and leases must always specify the payment terms applicable to the transaction. J&J companies, through J&J Finance Corporation [JJFC], may offer to finance customer's purchases of J&J products or services. Financing arrangements must be consistent with the prudent sales and lending practices and fair market value, and must be documented through appropriate written agreements. Leases represent an alternative method to "financing" customer's acquisitions of J&J products. Leases must likewise be consistent with fair market value and be reflected in a written agreement. Financing and lease arrangements must not be used as a mechanism to provide "free" or below market value items to customers in order to influence their selection of product. All such arrangements must be reviewed by the J&J Corporate Legal Department.

OBI does not engage in the practice of financing customers' purchases of products or services.

## Policy and OBI Procedures

Leases represent an alternative method of financing that is not an accepted business practice at OBI.

Should a request for this service be received, the requester should be referred to the Health Care Compliance [HCC] Department.

## Procedural Rules

1. J&J has established a financing corporation (JJFC), which is the only authorized organization that may set-up financing or lease arrangements to assist customers in purchasing products.
2. If in the future OBI desires to provide such support to customers, the arrangement must be reviewed for appropriateness and then comply with specific Health Care Compliance Guidelines.
3. Appropriate requests would then be forwarded to J&J Finance Corporation (JJFC). OBI must consult with the J&J Corporate Legal Department when entering into Marketing/Selling relationships with customers utilizing JJFC services.

*NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.*

## OBI Related Documents, Template and Forms

- Checklist for Commercial Sales Financing and Leases

## Questions and Answers:

Not applicable

## More Information

Not applicable

**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

Checklist for Commercial Sales Financing and Leases

LOANS

	Yes	No
Is J&J Finance financing the loan?		
Is there a written loan agreement that specifies the items being financed?		
Is the interest rate consistent with fair market value?		

LEASES

Is there a written lease agreement, which specifies the products leased and duration of the lease?		
Is the rent based on a flat periodic fee and not determined on the basis of utilization, referrals, or volume of business generated?		
Are the rental payments consistent with fair market value?		

IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT TO COMPLY WITH THE GUIDELINES OR CONSULT THE HCC DEPARTMENT BEFORE PROCEEDING.

Rental Space  
Section 7

# ORTHO BIOTECH

## Rental Space

### Overview

OBI may enter into arrangements with customers to lease space only where OBI has a bona fide need for the space. OBI may not enter into leases or agreements for space designed to compensate the customer for the purchase, recommendation, or use of OBI products. Payment to customers should be consistent with fair market value and should not be determined or proportional to the use of OBI products or services.

### Policy and OBI Procedures

#### Space Rental From our Customers

OBI may enter into arrangements with customers to lease space only where OBI has a bona fide need for the space. The rent paid to the customer should be consistent with fair market value and not determined in a manner that takes into account the value of any business generated for OBI.

OBI may not enter into rental of space from customers such as file space, drawer space or sample closet shelf space.

OBI may rent space from customer owned buildings for business purposes such as regional office space. In this instance, all procedures for procurement of regional office space must be followed. Compensation must be limited to fair market value.

#### Space Rental on Behalf of Customers:

OBI may not rent or lease space on behalf of a customer.

### ***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

### OBI Related Documents, Template and Forms

- Checklist for Space Rental Agreement

### Questions and Answers

**Q1:** I am sponsoring a speaker program for one hour at a hotel; the customer would like to use the space for the remainder of the day for their business meeting. Can I pay for the entire event?

**A1:** No. You can only pay for the part of the rental that applies to the speaker program.

**Q2:** Can a OBI sales representatives pay for "prime" shelf space in a physician's sample closet?

**A2:** No. Leases of minimal space such as drawer, file cabinet or closet space are inappropriate.

### More Information

Not applicable

**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

**Checklist for Space Rental Arrangements**

	<b>Yes</b>	<b>No</b>
Does OBI have a bona fide need for the space?		
Is the premises rented more than a minimal amount of space?		
Is there a written lease identifying the premises rented, describing J&J's right to use the premises, and specifying a term which is no longer than J&J's need for the space?		
Is the rental fee consistent with fair market value?		
Is the rental based on a flat fee and not based on utilization of J&J products or other variable payment structures?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT TO COMPLY WITH THE GUIDELINES OR CONSULT THE HCC DEPARTMENT BEFORE PROCEEDING.**

**Investments in Customer  
Organizations Section 8**

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# ORTHO BIOTECH

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## Investments In Customer Organizations

### Overview

Investment arrangements are undertaken to share financial risk or gain as a part of a joint common venture. Johnson & Johnson [J&J] companies should only "invest" in or enter into joint venture arrangements where the company seeks to achieve such purposes and not as a means of conferring a benefit (e.g. financing, distributions) designed to encourage the use of J&J products or services. Under no circumstances should J&J companies invest in customer organizations or enter into joint ventures with customers without review by the J&J Corporate Legal Department.

### Policy and OBI Procedures

OBI does not engage in the practice of investing in customer organizations.

If any such request arises in the future, it should be referred to the Health Care Compliance [HCC] department.

*NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.*

### OBI Related Documents, Templates and Forms

Not applicable

### Questions and Answers

**Q1:** May OBI or some other J&J company provide a loan for, or otherwise finance, all or a portion of the customer's portion of the investment?

**A1: No.** Customers are required to put their own money at risk. J&J does not act as a consumer or commercial lender, except to finance, through J&J Finance Corporation, the purchase or lease of OBI products and services at fair-market rates.

### More Information

Not applicable



# ORTHO BIOTECH

## Site Visits

### Overview

Customers and Healthcare Professionals may visit OBI administrative offices, training facilities or plants. The purpose of these visits can be to discuss potential business opportunities, provide education or training related to OBI's products, and other company information.

### Policy and OBI Procedures

In general, reimbursement for a customer's expenses associated with company facility visits are inappropriate, except when the customer is participating in a training program relating to the use of OBI products or services. However, in certain limited circumstances, it may be appropriate for OBI to reimburse expenses if the customer or potential customer will be visiting OBI for a legitimate business purpose.

OBI should establish a program for such visits, which may include an agenda of planned meetings, presentations, or educational seminars made by company personnel throughout the day. Furthermore, travel expense reimbursement may be made only in accordance with established OBI policy on corporate travel and reimbursement, and should be processed through a BTA account (Travel Expense Reimbursement Section #11)

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL***

### OBI Related Documents, Templates and Forms

- Site visit checklist

### Questions and Answers

**Q1:** If I fly a customer or potential customer to Raritan to play golf or attend a dinner and show, may I reimburse the customer's travel expenses if we stop by for a tour of the OBI on our way to the golf course or restaurant?

**A1:** No. It is inappropriate to reimburse a customer's expenses for a visit within the purpose of entertainment, or to reimburse expenses for a trip that is mainly for entertainment but includes a "token" visit to a company facility.

**Q2:** May healthcare professionals use our site meeting facilities for free?

**A2:** No. We may either donate use of our facilities to a charitable organization or charge the customer. In either case, this use must be documented. For a donation, the customer must meet the requirements of a charitable organization.

**Q3:** Do the guidelines only apply to site visits, or do they apply to other types of visits to J&J facilities by customers or potential customers?

**A3:** The guidance document is meant to be broadly applicable to visits by customers or potential customers to J&J company facilities, when a J&J company wishes to reimburse the customer's reasonable travel and meal expenses. Site visits to J&J administrative offices, customer visits to discuss potential business deals, or visits where education and training will take place are the types of visits that are covered by the guidance document. Appropriate signed and approved consulting agreements must be in place.

*If you are unsure about whether you may reimburse a customer's or potential customer's expenses for a company facility visit, you may contact your Health Care Compliance Department, or an appropriate company supervisor.*

**More Information**

- Travel Expense Reimbursement Guideline-Section #11
- Arrangements to Obtain Consulting and Other Services from Customers Guideline – Section #1

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**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

## Site Visit Checklist

Customer Name: \_\_\_\_\_ Date: \_\_\_\_\_

	Yes	No
1) Purpose of site visit is for customer/healthcare professional to provide education or training on OBI products or services.	<input type="checkbox"/>	<input type="checkbox"/>
2) Tour or site visit is for organization's decision makers to better understand OBI business.	<input type="checkbox"/>	<input type="checkbox"/>
3) Attendees are evaluating or whether to partner with OBI on business-related issues.	<input type="checkbox"/>	<input type="checkbox"/>
4) Site visits occur at an OBI facility.	<input type="checkbox"/>	<input type="checkbox"/>
5) Potential reimbursement of attendees will be limited to their reasonable, documented travel expenses.	<input type="checkbox"/>	<input type="checkbox"/>
6) Travel arrangements will be made by the appropriate OBI employee using an approved BTA.	<input type="checkbox"/>	<input type="checkbox"/>
7) Vice President supports/approves visit.	<input type="checkbox"/>	<input type="checkbox"/>

IF THE ANSWER TO ANY OF THESE STATEMENTS IS NO, RESTRUCTURE THE ARRANGEMENT OR CONSULT WITH YOUR SUPERVISOR AND HCC DEPT. IN ADDITION, FOLLOW GUIDELINES IN THE OBI BEST PRACTICES GUIDELINES FOR TRAVEL EXPENSE REIMBURSEMENT SECTION #11.



# ORTHO BIOTECH

## Entertainment and Gifts

### Overview

This section follows the American Medical Association (AMA) Code of Conduct Guidelines on providing meals, entertainment, and gifts to physicians. OBI applies the same guidelines to all health care professionals.

### Policy and OBI Procedures

Meals, entertainment, and gifts may be provided to health care professionals and reimbursed in accordance with the OBI Travel and Entertainment Policy. Gifts, meals and entertainment may only be provided in connection with sales calls, business decisions, or attendance at Ortho Biotech sponsored events.

Meals and Entertainment	\$ 20 Breakfast \$ 40 Lunch \$125 Dinner/Entertainment/Event Per Person
Healthcare Professional Nominal Value Gifts	\$25 per healthcare professional
Patient-related Gifts	\$125 per healthcare provider each six months
Meals, Entertainment, Gifts to Government Employees	Special guidelines apply. See Gratuities to Government Employees Section #14

OBI personnel should not provide tickets, coupons, vouchers, or similar items redeemable for meals or entertainment when not accompanied by an OBI employee.

Meals and entertainment provided to healthcare professionals should be recorded as Travel and Entertainment on the Field Sales Expense Report or Box 11 (business entertainment) of the Home Office Expense Report. The amount, location, name(s) of attendee(s), should be recorded on the expense report. Expenses for healthcare professionals' family members, spouses, etc., generally are not covered. However, there are exceptions. (See Q&A below or contact your manager).

Gifts provided to healthcare professionals should be expensed in the miscellaneous section on the Expense Report. These gifts should be nominal in value (<\$25) and infrequent. Patient related gifts (textbooks) are limited to \$125 each/6 months.

Due to the fact that health care professionals can only receive \$125 in patient related gifts per six months, it is necessary to individually track their gifts. Product Specialists are required to prepare a tracking form to record gifts given to physicians. The form should be sent to the Health Care Compliance Department. Responsibility of tracking shared physicians is determined by primary specialty. The amount, vendor, name(s) of recipient(s), and business benefit should be described in the supporting information for these expenses on the expense reports. Take care to include full names and correct spelling. Promotional

giveaways should be limited to the items purchased by the franchise marketing department. These items will be purchased by the franchise marketing teams and distributed by the field.

Events sponsored as entertainment should be charged to the OBI sponsoring group's American Express (Amex) Business Travel Account (BTA) where available. The owner of the event is responsible for ensuring that the value of the entertainment and/or gifts provided does not exceed the per-person limits listed above. (See Travel Expense Reimbursement Best Practice Guidelines Section #11).

Expense reports/BTA account reconciliation's should be completed with appropriate receipts and documentation as specified in the OBI Travel and Entertainment Policy and forwarded to the prepares' supervisor for approval.

The initiator of the expense is responsible for ensuring that all reimbursements are in compliance with the OBI Travel and Entertainment Policy and with AMA guidelines. Routine audits will verify the adequacy of receipts and documentation, as well as the legitimacy of the underlying activities.

See Entertainment and Gifts process flows in Section 10-6.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

#### **OBI Related Documents, Templates and Forms**

- Patient Related Gift Tracking Form

#### **Questions and Answers**

**Q1:** Can OBI representatives provide a physician with a free stethoscope or medical textbook/CD-ROM?

**A1:** Yes. Consistent with the guidelines, educational materials or medical equipment that are primarily used for patient treatment or benefit may be provided to health care professionals on an occasional basis if they meet the patient related gifts criteria.

**Q2:** Can I provide a free computer, fax machine, business software, to a physicians office?

**A2:** No. Computers, fax machines, or similar equipment are not of modest value and may readily be used for purposes unrelated to the use of J&J products or communications with J&J.

**Q3:** Can OBI representatives take a physician to dinner as part of a sales call?

**A3:** Yes. Dinners as a part of routine sales calls are permitted as long as the value of any meals and entertainment is consistent with the guidelines. However, it is not acceptable to give the physician a gift certificate for his or her use, or to otherwise pay for a physician's meal, that is not part of a sales call.

**Q4:** Can the physician's spouse accompany the physician to a dinner that is part of a sales call and have their dinner expensed?

**A4:** Yes. While we do not normally recommend it; a physician spouse's entertainment can be expensed. However, the combined entertainment (physician and spouse) must be captured and reported in the expense report for that physician. The expense (per person) must not exceed the \$125 per person limit.

**Q5:** Can we provide \$250 to fund a physician's office Christmas party?

**A5:** No. Gifts may not be provided to physicians or groups unless they primarily entail a patient benefit and are of modest value.

**Q6:** Can I take a hospital administrator to a baseball game or other sporting event?

**A6:** Yes. OBI employees may meet with healthcare professionals in connection with a modest entertainment event. However, it is not permissible to provide healthcare professionals with tickets that they may use on their own.

**Q7:** If Clinical Affairs entertains a customer in relation to a clinical study, does the value of that dinner apply to the meal and entertainment guidelines?

**A7:** Yes, It applies to the dollar amounts indicated in the guidelines.

**Q8:** Can I entertain a physician who also works as a government employee?

**A8:** Yes. However, it must only take place at their non-government place of business and must have no relationship with their government activities. For government employees without a private practice only, entertainment is limited to nominal events at the government site and gifts are prohibited.

**Q9:** Do home office promotional giveaways count towards the Entertainment & Gifts Guidelines dollar values?

**A9:** No. As long as they are less than \$25 in value and are provided by the home office marketing department.

**Q10:** Can I bring a Health Care Provider to a charitable event that OBI sponsored?

**A10:** Yes. However the fair market value of the entertainment/event needs to be recorded in the Navigator profile. (See Charitable Contributions Guideline #17)

**Q11:** Can a sales representative provide unrestricted grants to physicians and charge these sales through as an expense report?

**A11:** No. Grants are not paid through an expense report. Additionally, there are no unrestricted grants. The issuance of grants must follow the new Educational Grants/Research Grants/Speaker Programs policy and follow the HCC guidelines.

**Q12:** Can OBI run a speaker program and dinner cruise for the Veteran's Administration [VA] and invite the physicians and their spouses?

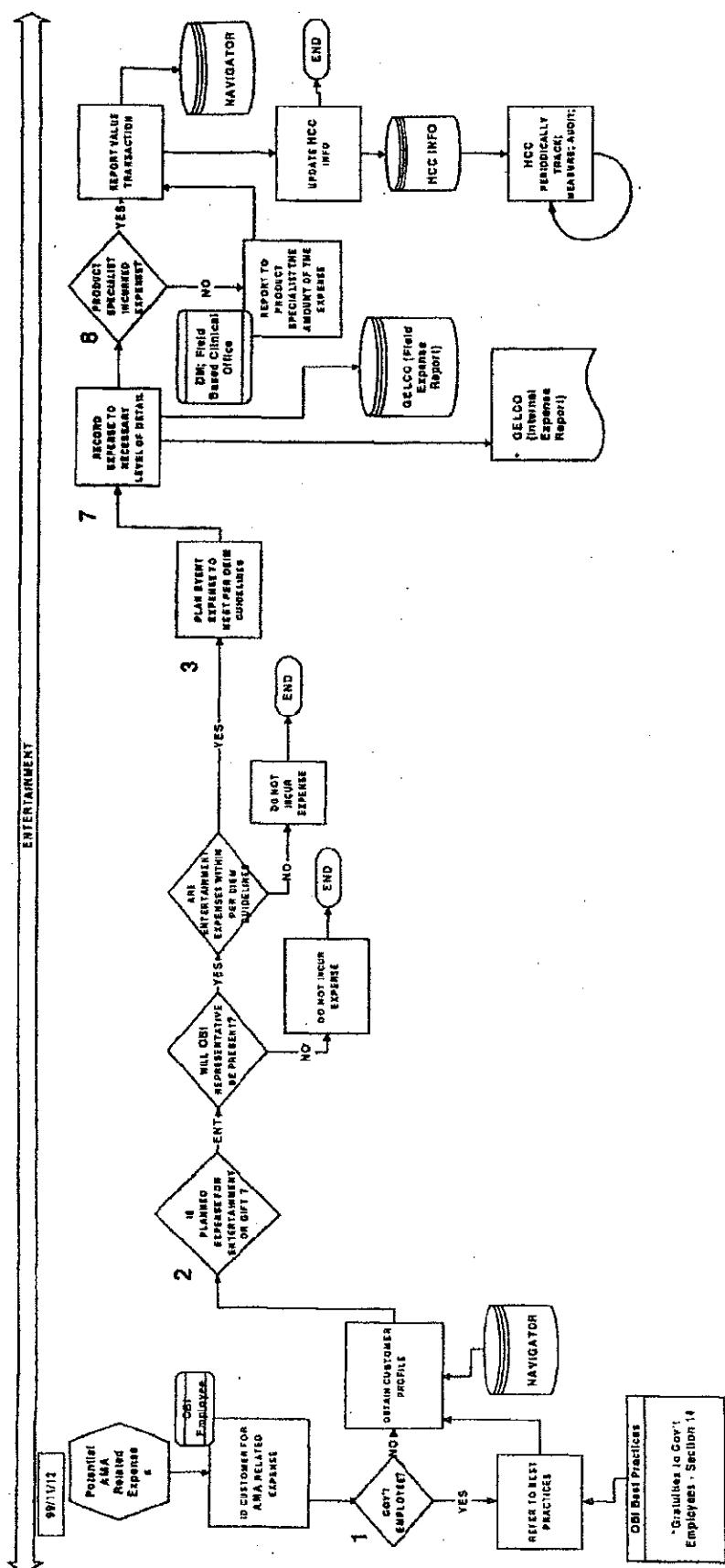
**A12:** No. These are government employees who may not be offered or accept entertainment/gifts. However you may offer such a program to non-government employees, with their spouses, as long as the cost is within the \$125 per person meal and entertainment limit.

**Q13:** Is the Guidance Document on Entertainment and Gifts applicable only to licensed health care professionals, or to administrators and other health care business people as well?

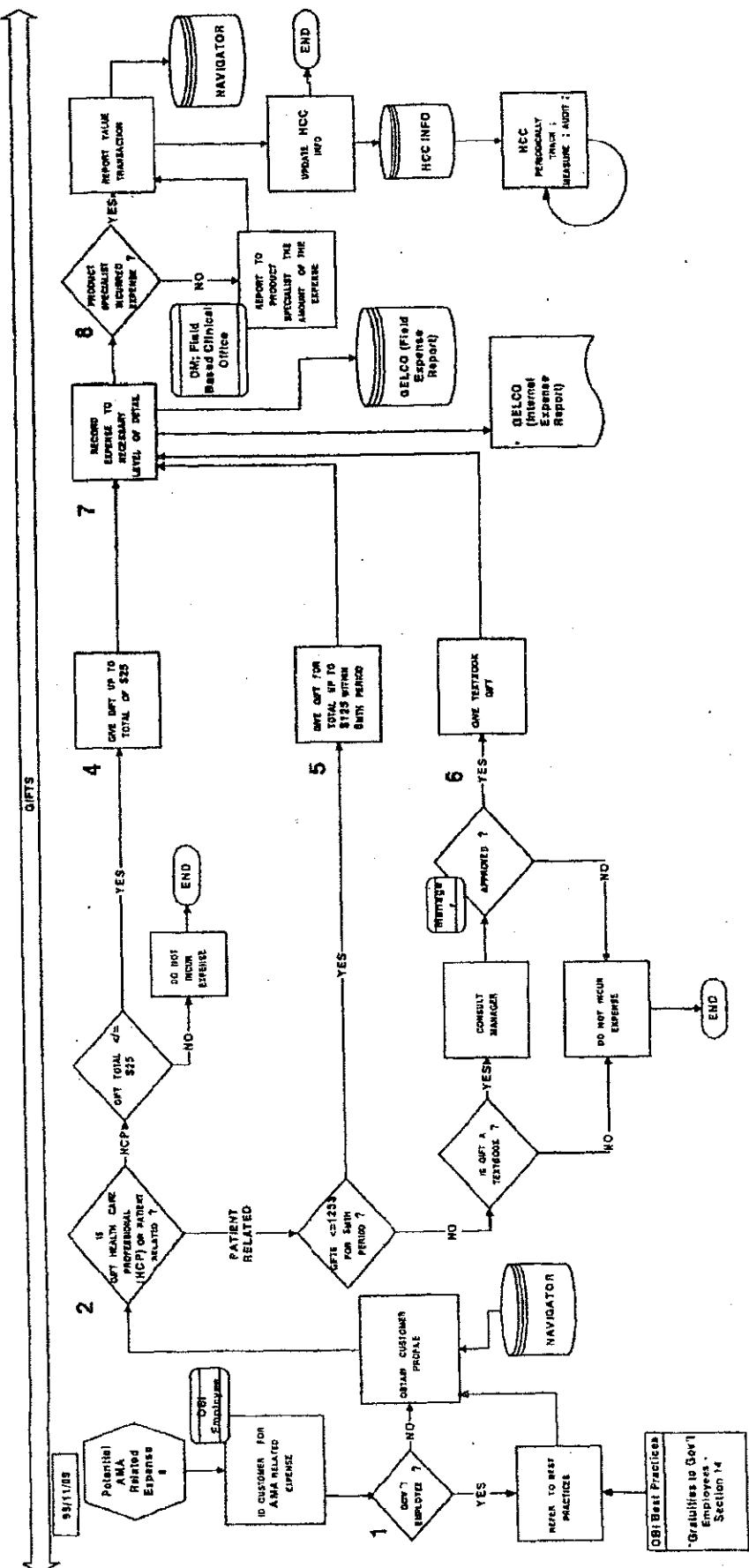
**A13:** No. It is applicable to all health care professionals, as well as to business people, such as administrators.

#### **More Information**

- Travel and Expense Guideline #11
- Charitable Contributions Guideline #17



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## Entertainment & Gifts Key Process Steps

- 1 - If the planned expense is for a government employee, check OBI Best Practices for government employees
- 2 - Determine if the planned expense is for:
  - Entertainment at which an OBI representative will be present
  - Gift for Health Care Professional (HCP)
  - Gift that is patient related
- 3 - If the expense is for entertainment, plan event to meet per diem guidelines
- 4 - If the expense is a gift for a HCP, plan a gift for a total of up to \$25
- 5 - If the expense is a gift to a HCP that is patient related, plan a gift for a total of up to \$125 in a six month period
- 6 - If the expense is for a textbook and the textbook is over \$125, obtain management approval
- 7 - Record the expenses
- 8 - If the expense has been incurred by other than the product specialist, report the amount of the expenses to the product specialist

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**ORTHO BIOTECH**

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**OBI Related Documents, Templates and Forms**

## **PATIENT RELATED GIFT TRACKING FORM**

**(\$125 PER HCP PER SIX MONTHS)**

\*Medical Education number can be found in your Territory Data books.

Travel Expense  
Reimbursement Section 11

# ORTHO BIOTECH

## Travel Expense Reimbursement

### Overview

This section incorporates and expands on J&J policy and the Travel and Entertainment policy.

### Policy and OBI Procedures

Travel paid on behalf of non-OBI employees must be in accordance with the Travel and Entertainment Policy. Specifically, OBI employees must not book travel for another individual on personal American Express cards.

Non-OBI-employee travel must be booked on an OBI American Express Business Travel Account (BTA) by the OBI employee authorizing travel. In the event that the BTA cannot be used, proper receipts and documentation must be submitted to OBI for reimbursement through PACT.

**Travel may be provided to non-OBI employees only if it is related to**

- Interviews
- Consulting agreements to provide services to or on behalf of OBI
- Employee's spouse or other travel approved by management in accordance with the Travel and Entertainment Policy (President's Cup)
- Site visits that comply with the OBI Best Practices Guidelines on Site Visits

**Travel may not be provided to non-OBI employees if it is related to**

- Entertainment
- Travel to meetings or conventions where the individual is not contracted to provide a service for OBI
- Attendance as a student at a CME course

**American Express Business Travel Account (BTA) Process Steps**

- Travel for a non-OBI employee's airfare, lodging, and ground transportation should be processed through a BTA account. Please contact the Finance Department for detailed BTA procedures.
- Complete BTA Log Form and obtain proper management approval (Field-Regional Business Director or Home Office-Manager)
- Send completed BTA Log Form to J&J Travel and OBI Finance

See Travel Expense Reimbursement process flows in Section 11-4.

**NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL**

**OBI Related Documents, Template and Forms**

- BTA Log Form

**Questions and Answers**

**Q1:** A physician is speaking about PROCRIT® to other physicians; can we reimburse his/her travel expenses?

**A1:** Yes. As long as there is a signed consultant agreement. Expenses must be in line with the Travel and Entertainment policy.

**Q2:** Can a presenting physician bring his/her spouse to an investigator meeting?

**A2:** Yes. The spouse may stay in the room as long as there is no additional cost for the room. All other expenses (air, meals) must be paid by the physician and are not reimbursable.

**Q3:** Can OBI reimburse travel expenses for a physician attending a speaker program?

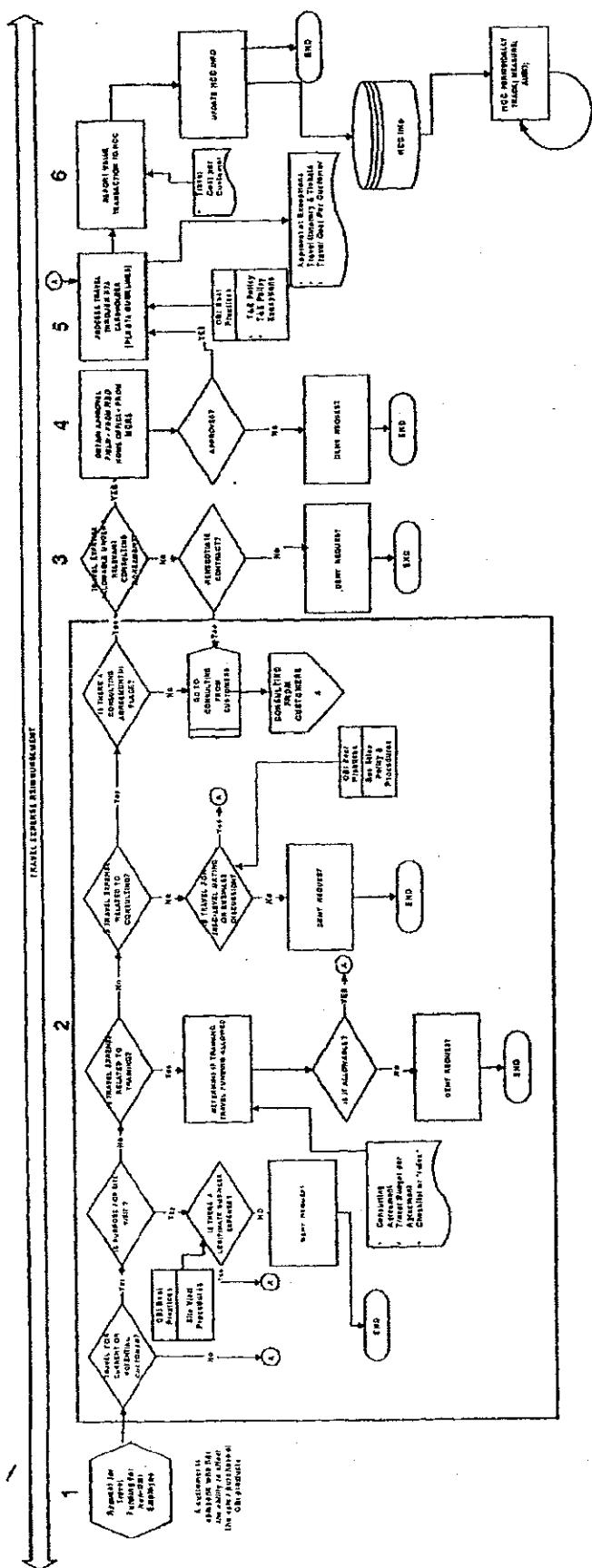
**A3:** No. Only the speaker, under a consulting agreement, may be reimbursed for travel expenses.

**Q4:** Can OBI reimburse travel expenses of physicians attending an investigator meeting?

**A4:** Yes. As long as there is a signed clinical study agreement.

**More Information**

- Travel and Entertainment policy
- OBI Consulting Agreement templates
- Arrangement to Obtain Consulting and Other Service from Customers Guideline #1
- Site Visits Guideline #9
- Entertainment and Gifts Guideline #10



## Travel Expense Reimbursement Key Process Steps

- 1 - Request Travel Funding for a Non-OBI Employee
- 2 - Check GUIDELINES for travel not covered under a consultant agreement
- 3 - Determine if travel expenses are allowable under the relevant consulting agreement
- 4 - If travel expenses are allowed, obtain approval:
  - Field - RBD
  - Home Office - MGR
- 5 - Process travel through BTA card holder according to BTA GUIDELINES
- 6 - Report the value of the transactions to HCC



**OBI Related Documents, Templates and Forms**

**Ortho Biotech Inc.**  
**BTA Log Form**

Please complete this form when utilizing the BTA for travel purposes. A copy of this form needs to be sent to J&J Travel as well as OBI when booking travel arrangements. Please obtain proper management approval prior to submission. Please contact Finance for a copy of the BTA procedure document to obtain a definition of the fields below.

Requestor / Originator Name: \_\_\_\_\_

Department Number / Cost Center: \_\_\_\_\_

Franchise (If applicable): \_\_\_\_\_

Division: \_\_\_\_\_

Name of Traveler: \_\_\_\_\_

Date of the Request: \_\_\_\_\_

Event Date: \_\_\_\_\_

Purpose of the Travel: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Service Requested (airfare, ground transportation, lodging) and Vendor name if  
known: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Traveler's Business Affiliation (Company, Name, Title, and/or Relationship to OBI – applicable to  
consultants or investors):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature Approval ( Field – Regional Business Director, Home Office – Manager):

Name (Print)

Title(Print)

Signature

Free Goods and Patient  
Assistance Section 12

# ORTHO BIOTECH

## Free Goods and Patient Assistance

### Overview

This section pertains to OBI's policy and procedures regarding "free goods" furnished to customers. Free goods are items that are furnished to customers at no charge and are not contingent on any purchase or commitment to purchase other OBI products or services. For example, a "free" product under a "buy one, get one" arrangement is not considered to be free for purposes of this guidance document but would constitute a discounting arrangement. OBI may provide free products to customers as part of patient assistance programs, clinical trials, and as samples under the PROCRIT® Experience Program.

### Policy and OBI Procedures

Free Goods and Services are provided through:

- PROCRIT® (Epoetin Alfa) Experience Program
- In conjunction with a bona fide clinical trial
- Patient Assistance Programs

If PROCRIT® is provided under the PROCRIT® Experience Program, the guidelines are as follows:

- The purpose is to familiarize physicians and patients with PROCRIT®
- Providing free goods must NOT be contingent on any purchase of J&J products
- The amount of drug provided through the PROCRIT® Experience Program is limited to that necessary to familiarize customers with the product
- The PROCRIT® Experience Program is designed in accordance with the requirements of the Prescription Drug Marketing Act (PDMA). Among other requirements, this demands that physicians request samples in writing and provide their signature
- The PROCRIT® Experience Program advises physicians that they may not bill third party programs for the distribution or use of free drug
- The physical product is labeled "SAMPLE DRUG- NOT FOR RESALE, INSURANCE BILLING OR REIMBURSEMENT"
- Free product provided for a physician's personal use is not permitted

**If PROCRIT® is being used in connection with a clinical trial, the following guidelines apply:**

- PROCRIT® may be furnished to physicians for use in bona fide clinical research trials that comply with the standards set forth in the Guidance Document on Consulting and Service Agreements.
- Clinical trials may not be used as "seeding" studies that are designed to induce physicians to use PROCRIT®.
- The OBI Clinical Study Agreement advises physicians that they may not bill third party payment programs for the distribution or use of free drug.
- The physical product is labeled "STUDY DRUG - NOT FOR RESALE, INSURANCE BILLING OR REIMBURSEMENT"

**Patient Assistance Programs**

OBI currently utilizes an independent vendor to implement the patient assistance programs. Documedics is the independent vendor that manages the utilization of the patient assistance programs.

**Description of services:**

**Patient Assistance Programs**

Qualified patients are put on a free or sliding scale program to receive PROCRIT® or LEUSTATIN® from their local pharmacy.

**Drug Replacement Program for Hospitals**

A hospital with patients with no benefits to cover PROCRIT® or LEUSTATIN® may be eligible for drug replacement. The patient must be considered uninsured for the product and meet the criteria established by the patient assistance program (free drug level status, not sliding scale) and the J&J Foundation. The hospital must prove that PROCRIT® was utilized and indicate the amount used.

**Drug Replacement for Physicians and Outpatient Clinics**

The provider's claim must be denied on appeal from the patient's insurance. The patient must meet the indigent status level (free drug status, not sliding scale), in order for the drug to be replaced to the provider.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.***

**OBI Related Documents, Template and Forms**

- Checklist on Free Goods, Clinical Trials, and Patient Assistance Programs

**Questions and Answers**

**Q1:** May a product specialist provide PROCRIT® samples to compensate a physician for product that failed to receive reimbursement?

**A1:** **No.** Any drug that is replaced must meet the specifications of the drug replacement program.

**Q2:** May a product specialist allow physicians to use PROCRIT® samples on multiple patients in order to gain experience with the product?

**A2:** Yes. The purpose of sampling is to familiarize physicians and patients with PROCRIT®. While it is reasonable that a physician may need to try PROCRIT® in more than one patient to gain experience with the product's properties, there is a limit to the number of patients that are required for this purpose.

**Q3:** May a product specialist provide PROCRIT® for a physician's personal use?

**A3:** No. If PROCRIT® were provided for the physician's personal use, it could be viewed as an inducement to use the product. The PROCRIT® Experience Program is not intended to encourage the purchase or use of PROCRIT®.

**Q4:** My physician is going to a third-world country. May I provide PROCRIT® for use in that country?

**A4:** No. A mechanism has been established by J&J to address charitable contributions of this type. Inquiries should be made to the Health Care Compliance Department.

**Q5:** May a product specialist provide sufficient product to allow a physician to initiate a clinical trial?

**A5:** No. Clinical trials may only be initiated through the OBI Clinical Affairs Department.

**Q6:** Can the drug replacement program furnish drug to an office that did not get reimbursed regardless of the patient's financial status?

**A6:** No. Patients must meet the financial criteria set forth by the drug replacement program.

**More Information**

- PROCRIT® Experience Program Policy & Procedures
- Standard operating procedures for Patient Assistance Programs

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**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

**CHECKLIST ON FREE GOODS, CLINICAL TRIALS AND  
PATIENT ASSISTANCE PROGRAMS**

	<u>YES</u>	<u>NO</u>
Are the free goods in no way contingent on the purchase of other J&J products?		
Is the free product provided as part of a sampling program consistent with the Prescription Drug Marketing Act designed to familiarize physicians and patients with a J&J product, or as part of a bona fide clinical trial that conforms with applicable J&J Guidance Documents?		
If a free sample product is a prescription pharmaceutical, will the sample be provided in accordance with a written physician request pursuant to the Prescription Drug Marketing Act?		
Has the recipient of the free product been informed that it should not bill for sample products or clinical study drugs?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT OR CONSULT WITH THE HCC DEPARTMENT.**

**Warranties  
Section 13**

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# ORTHO BIOTECH

## Warranties

### Overview

Johnson & Johnson [J&J] companies may offer warranties to purchasers or end user customers with respect to performance of their products. J&J companies generally may not offer warranties on competitor's products or on matters unrelated to the performance of J&J products. Warranties may implicate fraud and abuse prohibitions, trade regulation standards and product liability laws. All warranty arrangements or similar commitments must therefore be approved by the J&J Corporate Legal Department.

For the purpose of this Policy, warranties generally apply to medical devices or equipment.

### Policy and OBI Procedures

OBI does not offer warranty arrangements or similar commitments for our products or services to customers at this time.

Should a need to offer warranties arise in the future; approval by J&J Corporate Legal Department and OBI's Healthcare Compliance Department would be required.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.***

### OBI Related Documents, Template and Forms

- Checklist for Warranties

### Questions and Answers

Not applicable

### More Information

Not applicable

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**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

## Checklist for Warranties

	Yes	No
Is the warranty reflected in writing and provided in connection with the sale of a J&J product?		
Does the warranty specify the precise terms, limitations and conditions of the warranty and the method that the consumer must use to redeem the warranty?		
Does the warranty specify the remedy available and specifically exclude from the remedy any consequential damages and related medical costs associated with providing the warranted product?		
Does the warranty relate to a J&J product that does not meet the specified performance standards?		
Will the customer be provided with documentation of any free product furnished under the warranty, advised that it should maintain that documentation and advised that it may have an obligation to take into account free goods on cost reports or claims submitted to third party payors?		
For extended warranties, has the customer paid for the warranty or will the value of the warranty be reflected as a discount on the product?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT OR CONSULT THE HCC DEPARTMENT.**

Gratuities to Government  
Employees Section 14

# ORTHO BIOTECH

## Gratuities to Government Employees

### Overview

This section follows the Ortho Biotech standards on providing gratuities to any government employee. WHILE THESE ARE JOHNSON & JOHNSON GUIDELINES, IT IS ALWAYS PRUDENT TO CHECK WITH THE POLICIES & PROCEDURES OF THE LOCAL GOVERNMENT INSTITUTIONS.

### Policy and OBI Procedures

#### **Gifts & Gratuities**

OBI personnel may not provide gifts to federal, local, or state government officials.

#### **Promotional Giveaways**

Promotional marketing items may be provided to government employees as long as the items are under \$25 in value.

#### **Entertainment and Meals**

Follow the dollar limits listed in the "Entertainment & Gifts" section.

Meals may only be provided to government employees if they are of "modest" value (e.g. pizza, bagels and sandwiches but not a lavish catered meal), and they must be provided on site at the VA hospital or government agency in connection with an in service training or sales call.

#### **Physicians who are employed by both government and for profit organizations**

The entertainment and gift guidelines may apply to physicians who have dual roles in both profit and non profit agencies. However you may only entertain physicians who have dual reporting responsibilities in their place of work that is not government owned or operated. Any entertainment of these physicians or government property is strictly prohibited. When entertaining these physicians, the Entertainment and Gifts Guidelines apply.

#### **Political Contributions**

Political contributions on behalf of OBI may only be made consistent with J & J Guidelines on Political Contributions in the United States.

No discussions or offers of employment should occur with government officials during the course of government contract procurement involving any J&J products or services.

**Educational Support for Government Physicians**

Funding for government physicians' attendance at continuing education programs may be provided through the Henry Jackson Foundation for the Advancement of Military Medicine or coordinated through the OBI Government Account Manager.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

**OBI Related Documents, Templates and Forms**

Not applicable

**Questions and Answers**

**Q1:** Are inservices and similar types of entertainment such as modest dinners allowed for VA physicians?

**A1:** Yes. However, it must take place on VA property. Appropriate monetary guidelines must be followed.

**Q2:** Can OBI hire an outside speaker who is a governmental employee to speak at an internal meeting of salespeople to discuss reimbursement issues?

**A2:** No. If the speaker is a federal, state, or local government employee, OBI cannot provide any gifts, gratuities, or honoraria (including payment for travel costs or expenses) to the government speaker. This includes any physician, nurse, or other personnel who are employees of a Veteran's Hospital or other governmental health care provider. However, if a government employee wishes to speak without accepting any reimbursement, honorarium or entertainment it is allowed. Limited exceptions may apply, contact the Health Care Compliance for more information.

**Q3:** Can a sales rep give a gift of under \$25 in value to a government employee? For example, can the sales rep give a VA nurse a pen or mug with the OBI logo on it?

**A3:** Yes. A company may give a government employee a pen, mug, or other items of under \$25 value.

**Q4:** Can we engage a VA physician as a consultant? For example, can we hire a VA physician to serve on an advisory board, or to speak at a gathering of OBI sales people?

**A4:** No. Consulting arrangements with government employees including physicians are not permitted, except in very limited circumstances. For example, if a particular government employee possesses research or knowledge that is of great interest to OBI, and if that knowledge can not be readily obtained elsewhere, exceptions may be made. To enter such an arrangement, the government employee must obtain the explicit written consent of a representative of their employer who is legally authorized to give such consent. Without the employer's written consent by a duly authorized representative, OBI may not enter into a consulting arrangement with a government employee.

**Q5:** Can government employees be part of an advisory panel?

**A5:** Yes. But travel and meal expenses may not be reimbursed nor can an honorarium be paid.

**Q6:** Does this policy apply when government employees are attending functions outside the United States?

**A6:** Yes. All of the above policy statements apply to US government employees whether they are in the United States or traveling on an international assignment.

**Q7:** Can government physicians take part in and be reimbursed for their work in clinical studies?

**A7:** Yes. They may take part in studies but may not be reimbursed.

**Q8:** Can I use a VA physician as a speaker and pay them an honorarium?

**A8:** Yes. But you may not pay them an honorarium or pay their travel or meal expenses.

**Q9:** If the meal is more than their per diem amount can we pay the difference?

**A9:** No. You may not pay the difference between the per diem and the value of the meal.

**More Information**

- Arrangement to Obtain Consulting and Other Services from Customers Guideline #1
- Entertainment and Gifts Guideline #10
- Travel Expense Reimbursement Guideline #11



# ORTHO BIOTECH

## Overview

OBI may offer coupons to end users such as patients under which the patient may receive a discount or rebate in connection with the purchase of OBI products. There are generally two types of coupons: Partial Value and Full value.

Partial Value coupons can be provided directly to consumers of OBI products or through physicians and managed care organizations. These programs must not expose the company to new best prices and must include language that identifies customer classes that cannot participate in the program.

Coupons providing free goods at full value represent patient sample starters and must follow Prescription Drug Marketing Act [PDMA] guidelines.

## Policy and OBI Procedure

All coupon programs should be approved by applicable Brand Management and the OBI Promotional Review Committee (includes Johnson & Johnson (J&J) Legal Regulatory representation). Special considerations may need to be given to Medicaid Best price thresholds. Consultation with Managed Care Finance is necessary. This initiative may only be offered with the approval of the HCC Department and Legal.

Partial Value Coupons can be provided to consumers either through a physician or third party (advertisement, etc.) as long as the program meets certain requirements and is approved by the OBI Promotional Review Committee. These requirements are:

- Partial value coupons must be at a minimal level and/or less than \$5.
- Programs that fall outside the minimal (\$5 level) must be below applicable product 's Medicaid/VA best price threshold and include provisions that will ensure against Medicare fraud.
- Patient coupon value cannot exceed customers out of pocket costs.
- Patient confidentiality must be maintained. Coupons should include appropriate language as it pertains to customer reimbursement and participation restrictions.

## **Procedural Rules**

1. Coupons must benefit the ultimate consumer or patient.
2. Permissible distribution channels include direct mailings, mass media such as newspaper inserts, physicians or other customers.

3. Confidential patient information may not be collected however demographic information may be collected if the patient is advised that it may be used with future promotions.
4. Coupons may be redeemed at point of sale or through patient rebate arrangements administered by J&J or a third party.
5. Coupons must contain language that prohibits use of the coupon by certain classes of patients as necessary.
6. Coupons may not be redeemed by patients receiving benefits under federal health care programs.
7. Coupons may not be redeemed in states with anti-kickback laws that apply to services reimbursed under commercial third party payor programs.

*NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL*

**OBI Related Documents, Templates and Forms**

- Checklist for Coupons

**Questions and Answers**

**Q1:** Can a coupon program be developed for a specific customer or Managed Care Organization [MCO]?

**A1:** Yes. As long as it meets dollar levels and government reimbursement requirements, and receives Brand, Managed Care Finance, and OBI Promotional Review Committee approval. Best price thresholds should not be exceeded.

**Q2:** Can we develop a coupon program that initiates therapy and provides product to a patient through a pharmacy?

**A2:** Yes. This generally is considered a sample coupon or patient starter sample program and must follow PDMA guidelines.

**Q3:** Can a coupon be applied towards a patient's managed care organization co-pay?

**A3:** Yes. As long as the coupon value does not exceed the co-pay amount. OBI Promotional Review Committee approval is necessary.

**More Information**

Not applicable

**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

## Checklist for Coupons

	Yes	No
Is the coupon redeemable by the patient?		
In the case of prescription products, will the coupon be redeemed through patient rebate arrangements?		
Will the coupon include a "carve out" for government patients and patients in "all payor" states, as well as other standard disclaimers?		
Can the coupon be redeemed on goods purchased at any distribution outlet?		
Will the value of the coupon be limited to the patient's actual-out-of-pocket expense?		
Has the J&J Corporate Legal Department reviewed the coupon?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT TO COMPLY WITH THE GUIDELINES OR CONSULT THE HCC DEPARTMENT BEFORE PROCEEDING.**



# ORTHO BIOTECH

## Promotional Giveaways

### Overview

This section addresses the use of gifts, trips, prizes, or the like as part of a sweepstakes or similar promotion to healthcare professionals. This practice is subject to substantial restrictions because it may be viewed as an inappropriate inducement for the purchase of Ortho Biotech products.

### Policy and OBI Procedures

Under no circumstances may Ortho Biotech offer gifts, trips, prizes or the like as part of a sweepstakes or similar promotion to healthcare professionals as an inducement for them to purchase Ortho Biotech products or services, to purchase specified volumes of Ortho Biotech products or services, or for the expedited completion of a research study.

Ortho Biotech may sponsor sweepstakes or the like to patients in connection with the promotion of over the counter products, so long as:

1. No purchase is necessary to enter the sweepstakes
2. The program does not require the patient to obtain products from a particular pharmacy or other source of supply.

Gifts/prizes offered may not be greater than the AMA patient care related gift guideline of \$125 every six months or the AMA nominal gift guideline. (See Guideline on Entertainment & Gifts - Section #10) Ortho Biotech may offer special packages of products which contain free samples of other products or similar items subject to compliance with discount reporting obligations.

*NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.*

### OBI Related Documents, Templates and Forms

Not applicable

### Questions and Answers

Q1: Are pens, note pads and other sales "leave behind" items allowed?

A1: Yes. Refer to the Guidance Document on Entertainment and Gifts under nominal gifts.

**Q2:** How does one differentiate between a gift and an inducement?

**A2:** If the item of value is given contingent on getting something back in return and/or it is not of modest cost as defined by the Guidance Document it can be considered an inducement.

**Q3:** Is it allowable to have a contest at a booth during a medical meeting for a fruit basket or something of the like?

**A3:** Yes. The giveaway should be of modest value

**More Information**

- Entertainment & Gifts Guideline #10

**Charitable Contributions**  
**Section 17**

# ORTHO BIOTECH

## Charitable Contributions

### Overview

In general, decisions on charitable contributions are the responsibility of department heads, their designees or the OBI corporate contribution's staff. In the field sales organization, decisions on charitable contributions are made in accordance with established signature authorization. No other employee may commit company resources to charitable causes without proper authorization.

### Policy and OBI Procedures

All charitable contributions will meet the following requirements:

- requests must be received in writing and must explain the purpose for which the funds will be used
- requests must meet the requirements outlined in the J&J Guidelines for Giving
- recipients must be from a tax exempt organization with valid 501 (C)3 tax status
- contributions will be provided without condition of purchase, use or recommendation of OBI products
- OBI may not offer to make contributions in the name of a customer or make a contribution to an organization of the customer's choice
- OBI's contribution cannot comprise a substantial portion of the recipient's budget
- The contribution should be related to a disease state or community initiative of interest to OBI

The receiving organization must commit in writing that no goods or services were provided in exchange for payment.

Charitable contributions given by OBI in any form will follow the J&J Guidelines for Giving. Please see Free Goods & Patient Assistance (Section #12), for guidelines on giving free product.

### Johnson & Johnson Guidelines for Giving:

Johnson & Johnson makes cash contributions to organizations that are active primarily in the following areas:

- Health
- Education
- Employment and training
- The family
- Environment
- People with disabilities

Johnson & Johnson supports project requests that can be clearly evaluated; and is not able to support the following kinds of requests:

- Appeals for unrestricted funds
- Scholarships to individuals
- Direct grants to individuals
- Loans
- Trips or tours
- Endowments of any kind
- Sectarian and religious organizations that do not serve the general public on a nondenominational basis
- Capital requests (building or endowment funds) are generally not supported
- Political, fraternal, or athletic groups

See Charitable Contributions process flow in Section 17-5.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP 1 VIOLATION AND COULD RESULT IN DISMISSAL.***

**OBI Related Documents, Templates and Forms**

- Checklist for Charitable Contributions
- OBI Charitable Contribution Approval Letter
- OBRA Form and Letter
- Grants/Charitable Contributions Request Form

**Questions and Answers**

**Q1:** Can Ortho Biotech make a charitable contribution to a hospital customer to be used to build an educational center? In other words, can a J&J company contribute to capital projects, also known as "bricks and mortar" projects?

**A1:** No. Ortho Biotech can not make a "bricks and mortar" contribution for the development of any buildings, including an educational center. Ortho Biotech should check the J&J Corporate Contributions Policy for further guidance.

**Q2:** Can Ortho Biotech pay \$500 to Cancer Care, assuming Cancer Care is a 501(c)(3) organization, for four players to play a round of golf?

**A2:** Yes. This would constitute a charitable, deductible contribution. However, if Ortho Biotech pays \$50 per player (the fair market value for the round of golf), the payment may simply represent a fee for service, and there may be no charitable contribution ascribed to the payment. In either case, Ortho Biotech's employees, and not their customer guests, should play.

**Q3:** Is it permissible for Ortho Biotech to contribute \$500 to NMAC at the request of a customer hospital, or if a customer hospital collects \$500 from Ortho Biotech on behalf of the NMAC for a round of golf for four players?

**A3:** No. Ortho Biotech may not make a contribution at the request of a customer, nor may Ortho Biotech contribute funds to a customer that will be ultimately turned over to a charitable 501(c)(3) organization, since it may be interpreted that one of the main purposes of such a contribution would be to cull the customer's good favor.

**Q4:** Can Ortho Biotech buy a booth at a National Kidney Foundation Health Fair for \$5,000, assuming the National Kidney Foundation is a tax exempt 501(c)(3) organization?

**A4:** Yes. But, this activity would not be considered a charitable contribution. It would be considered a legitimate marketing activity, assuming the \$5000 represents the fair market value for the opportunity for Ortho Biotech to establish a presence at the meeting. This reasoning would also apply to an organization that is not a tax-exempt charitable organization.

**Q5:** Can Ortho Biotech make a contribution to a 501(c)(3) customer organization for an educational meeting?

**A5:** Yes. This activity may not be considered a charitable contribution, but instead might be considered to be an educational grant to the customer. The grant should be made in accordance with the Guidance Document on Educational and Research Grants.

**Q6:** I am currently a sales rep in the Boston area. A physician researcher approached me to request funding for his Phase IV clinical study for the use of PROCRIT® in an orthopedic patient. Can I contribute to his Study?

**A6:** No. OBI's policies prohibit contributions to individuals. However, it may be allowable as a clinical research arrangement. Contact the Clinical Affairs department.

**Q7:** I am making a cash contribution of \$50 to a local charity. I gave them a personal check. Can I process the reimbursement on a Travel and Expense [T&E] form?

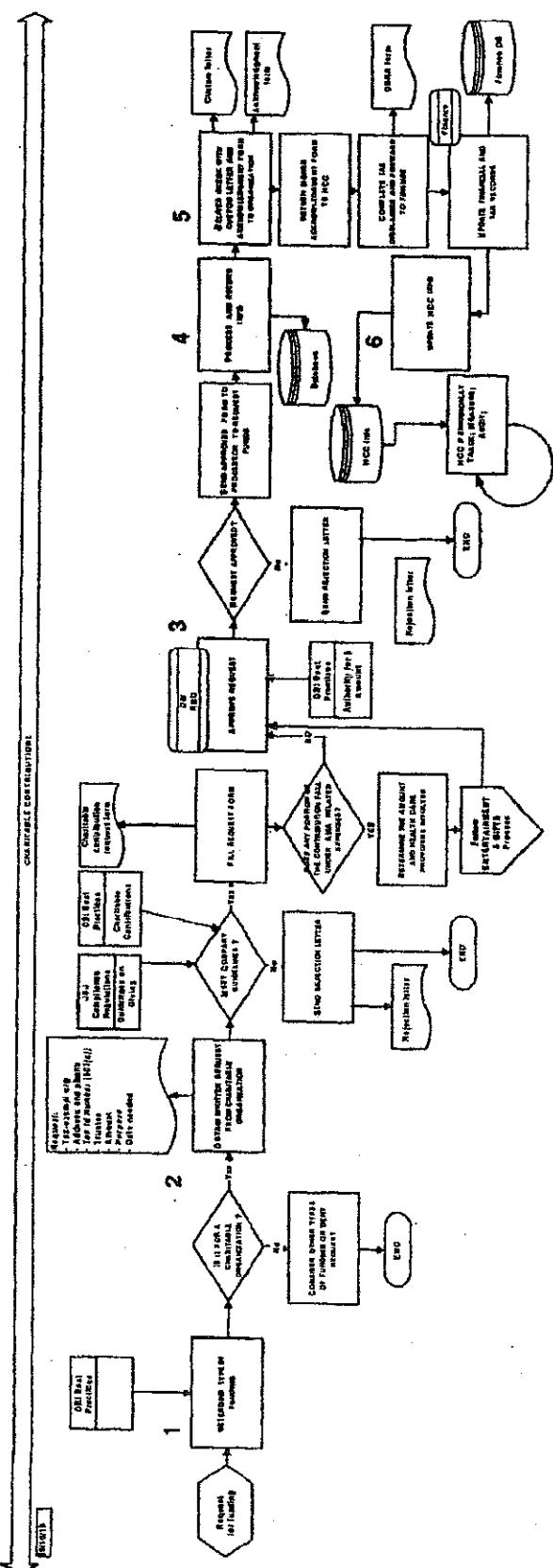
**A7:** No. Cash contributions may only be processed by requesting a check in PACT. They may not be processed on a T&E form.

**Q8:** Can I purchase a table at the Leukemia Society of America's annual dinner and invite customers to sit at the table?

**A8:** Yes. As long as an OBI representative will be present and the cost for the meal (net of charitable component) meets the Entertainment and Gifts Guidelines in Section #10.

**More Information**

- Educational Grants Guideline #3



## Charitable Contributions Key Process Steps

- 1 - Determine if the funding fits guidelines for charitable contributions
- 2 - Obtain written request from charitable organization
- 3 - Fill out the request form
- 4 - Obtain approval - <\$3000 - DM; >\$3000 - RBD
- 5 - Process and record information through PACT/Marketcheck
- 6 - Deliver check with custom letter and acknowledgement forms
- 7 - Submit all paperwork to HCC

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**ORTHO BIOTECH**

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**OBI Related Documents, Templates and Forms**

## CHECKLIST FOR CHARITABLE CONTRIBUTIONS

	<u>YES</u>	<u>NO</u>
Is the recipient a tax-exempt charitable organization (501 (C) 3 certified)?		
Does the contribution meet the standards outlined in the J&J Guidelines for Giving?		
Does the contribution represent a modest portion of the organization's overall budget?		
Is the purpose of the contribution related to a disease state or community initiative of interest to OBI?		
Is the contribution provided without condition of purchase, use, or recommendation of OBI products?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT OR CONSULT WITH THE HCC DEPARTMENT.**

**ORTHO BIOTECH**

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700 U.S. Highway 202  
P.O. Box 670  
Raritan, NJ 08869-0670

Date

Organization Name  
Contact  
Address  
Address

Dear XXXX:

Enclosed is a check in the amount of \$XXXX. This check represents our support of  
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

In order to comply with the Omnibus Budget Reconciliation Act of 1993 (OBRA), please sign  
the attached form where required and provide the requested  
documentation and/or information for the items checked.

If you have any questions, please call me at (908) 704-XXXX.

Cordially,

Enc

**ORTHO BIOTECH**

700 U.S. Highway 202  
P.O. Box 670  
Raritan, NJ 08869-0670

Date

Organization Name  
Address  
Address

**Please Return to:**  
Ortho Biotech  
Attn: XXXXXXXXXXXX  
700 U.S. Highway 202  
Raritan, NJ 08869

In order to comply with the Omnibus Budget Reconciliation Act of 1993 (OBRA), we would appreciate your completing the information below and returning the form and any supporting documents to us within one week of receiving your donation.

I certify that these funds represent a gift to our organization with no return benefit derived by Ortho Biotech Inc. If there is a derived benefit to the corporation, I have attached a statement specifying that benefit and its value.

Cash Contribution Received: \$ \_\_\_\_\_

Date Received: \_\_\_\_\_

**Important:** Is your organization considered to be tax exempt by the I.R.S. under Section 501 (C)(3) of the internal Revenue Code?

YES \_\_\_\_\_ NO \_\_\_\_\_

In cases where a business gives a donation of \$75 or more for a special event (dinner, golf/tennis tournament, etc.), it is also necessary to determine what amount of the commitment is designated as a charitable donation. The dollar amount separate and apart from expenses incurred in the event which shall be considered a charitable gift is:

Charitable Gift Amount: \$ \_\_\_\_\_

The information above is provided for the purposes of complying with IRS requirements and is accurate to the best of my knowledge. I understand that penalties may be imposed by the IRS on organizations that fail to make the required disclosure.

Authorized Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Discount, Rebates, and  
Contracting Concessions  
Section 18

# ORTHO BIOTECH

## Discounts, Rebates, and Contracting Concessions

### Overview

This policy provides procedures for approval and communication for all OBI sales contracts. This includes sales contracts originating at Johnson & Johnson Health Care Systems [JJHCS] or OBI. Johnson & Johnson [J&J] companies may offer discounts, rebates, credits, and other price concessions to customers. Discounts and other price concessions may be offered to entities such as wholesalers that purchase products directly from OBI or to end user customers such as hospitals, pharmacies, or physicians who purchase products from a distributor under a charge back or rebate arrangement. The level of any price concession may be based on the volume or value of items purchased or used by a customer, market share, patient medication compliance or similar measures. This program may only be developed with the approval of the Law Department.

### Policy and OBI Procedures

In all cases, discount levels must be consistent with established J&J pricing policies with respect to particular products, including policies relating to the level of discount offered to particular classes of customers.

Discount arrangements should be documented in a contract template.

Discounts may not be offered only on those units of a product, which are dispensed, to a patient in connection with a "switch" from a competitive product.

It is sometimes appropriate to exclude patients whose care is covered under federal health care programs from both the calculation of the discount level and the utilization to which discount levels apply.

OBI must furnish the customer with documentation, which enables the customer to establish its net acquisition cost.

The level of discount may be expressed as a percentage, per unit, or similar amount and may be based upon the volume of OBI products or services purchased, sold or used by a customer.

Discounts may apply to units purchased, sold, or dispensed by a customer.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL***

### OBI Related Documents, Templates and Forms

Not applicable

### Questions and Answers

Not applicable

### More Information

Not applicable

Inventory Exchanges and  
Conversion Funding  
Section 19

# ORTHO BIOTECH

## Inventory Exchanges and Conversion Funding

### Overview

In connection with an agreement to purchase or stock Johnson & Johnson [J&J] companies' products, J&J companies may exchange J&J products for the customer's existing inventory of competing products under the standards described below. However, it is generally impermissible to fund other customer costs associated with the conversion to J&J products.

OBI does not engage in agreements to purchase or stock its products in exchange for customers' existing inventory of competing products.

### Policy and OBI Procedures

While it may be appropriate to enter into agreements providing specific guidelines are followed, OBI does not consider this a standard business practice.

Should inventory exchanges and conversion funding be a consideration in the future, approval by J&J Corporate Legal Department and OBI's Healthcare Compliance Department would be required.

**NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.**

### OBI Related Documents, Template and Forms

Not applicable

### Questions and Answers

Not applicable

### OBI Related Documents, Template and Forms

Not applicable



# ORTHO BIOTECH

## Combined Product and Services

### Overview

Combined products and services may range from arrangements that involve a discrete product line to discounts based on purchases across several lines of business. Combined product and service agreements can involve not only health care items, but also health care services such as consulting services, extended warranties, or the like.

As a general matter, combined products and services are a permissible and rational way of selling, however, such arrangements should be reviewed and approved by the OBI Health Care Compliance Department and Law Department.

### Policy and OBI Procedures

OBI may not require a customer to purchase one product as a condition to having access to another. The customer should retain the option of separately purchasing the individual products included in the offering.

The value of the discount must be allocated across all products within the offering and be reported to the customer in that fashion – OBI may not allocate the entire value of the discount to one product. If OBI provides free goods to a customer as part of a combined product offering, the total net discount effect must be reported to the customer.

OBI may not combine products and services as a method of providing free goods to a customer.

When considering a program/ service offering to a customer, you must first determine if the program/service is a product that you must charge for, a value added service that does not require a charge, or a charge optional program such as a non-CME Professional Education course.

***NON-COMPLIANCE WITH THIS POLICY IS A GROUP I VIOLATION AND COULD RESULT IN DISMISSAL.***

### OBI Related Documents, Templates and Forms

- Checklist for Combined Products and Service Offerings

### Questions and Answers

Not applicable

### More Information

Not applicable

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**ORTHO BIOTECH**

**OBI Related Documents, Templates and Forms**

### Checklist for Combined Product and Service Offerings

	Yes	No
Are multiple products or services being sold at a single price which is lower than the total amount that would be paid if the customer bought each of the products or services separately?		
Will the value of the discount be allowed among all of the products and services in the offering?		
If the value of the discount is known at the time of the sale, will the allocation of the discount among the products and services be reflected on the invoice?		
If the value of the discount is not known at the time of the sale, will the customer be advised of the allocation of the discount among the products and services in the offering?		

**IF THE ANSWER TO ANY OF THESE QUESTIONS IS "NO", RESTRUCTURE THE ARRANGEMENT TO COMPLY WITH THE GUIDELINES OR CONSULT THE HCC DEPARTMENT BEFORE PROCEEDING.**



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# ORTHO BIOTECH

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## Glossary

<b>AMA</b>	American Medical Association.
<b>AMA Code of Ethics Benchmark</b>	Meals and Entertainment – one event per person per six months, the value of which must be modest.  Nominal Value - \$25/ person – limit each six months.
<b>AMA Guidelines</b>	Patient Related Gifts – A \$100 per person limit per six months.
<b>Anti-kickback Laws</b>	Industry standards specifying limits on health care manufacturers' provision of gifts or educational support to physicians. (See Guidance Documents on Arrangements to Obtain Consulting and Other Services from Customers, Educational and Research Grants, Training Programs, Site Visits, Entertainment and Gifts, Travel Expense Reimbursement, and Free Goods and Services)
<b>Bona Fide Services</b>	Federal or state laws that prohibit the payment of anything of value to a person to induce the person to recommend a health care manufacturer's products.
<b>BTA</b>	Services which require the performance of actual duties and which are reasonably needed by the person paying for them. (Guidance Documents on Arrangements to Obtain Consulting and Other Services from Customers, Educational and Research Grants, and Travel Expense Reimbursement)
<b>CME Program</b>	Business Travel Account.
	Continuing Medical Education Program which is designed to provide education information concerning disease states or treatments, but which is not intended to promote a particular manufacturer's products. Johnson & Johnson may provide support for CME programs where it has no control or influence over the content of the program. (Guidance Documents on Educational and Research Grants, Entertainment and Gifts, and Travel Expense Reimbursement)

<b>Combined Product and Service Offering</b>	Combination of multiple items or services into a single "product" which may be purchased separately. In such sales, the document amount must be allocated proportionately to all products. (Guidance Documents on Free Goods and Services, Warranties, Discounts, Rebates and Other Price-Related Contracting Concessions, and Combined Products and Services)
<b>Consulting or Service Agreement</b>	Agreement under which a party agrees to provide valuable services which are legitimately needed by Johnson & Johnson for a price consistent with fair market value. A consulting or service arrangement is not a grant to a customer to perform activities, which principally benefit the recipient of the payment. (Guidance Document on Arrangement to Obtain Consulting and Other Services from Customers, Consulting and Services Provided to Customers, and Travel Expense Reimbursement)
<b>Customer</b>	Is any individual or company that has the ability to prescribe or the ability to influence the use of OBI's products.
<b>Customer Sponsored CME Program</b>	A CME program that is furnished by a customer, as opposed to a program offered by an independent CME provider. Johnson & Johnson can only provide direct costs of educational activities of customer sponsored CME programs. (Guidance Document on Educational and Research Grants)
<b>Deliverables</b>	The interim and final output that will be delivered by a supplier to OBI. Deliverables may be either service or physical in nature.
<b>Educational Grant</b>	A grant to a customer to prepare or distribute educational materials to providers or patients which primarily benefit the recipient of the grant and only incidentally benefits Johnson & Johnson. Educational grants may also be used to support fellowships. Educational grants may not be used to subsidize activities, which a customer is already required to, or customarily, performs as part of its business activities. (Guidance Document on Educational and Research Grants)
<b>Fair Market Value</b>	The value of an item or service negotiated in arms-length transactions, and which is consistent with the market price of competing items or service. (Guidance Document on Arrangements to Obtain Consulting and Other Services from Customers, Computer Hardware and Software, Commercial Sales Financing and Leases, Space Rental, Combined Products and Services, and Inventory Exchanges and Conversion Funding)
<b>Fellowship</b>	Educational grant to a hospital or other health care institution to support the medical training of interns, residents, or the like. In providing support for fellowships, Johnson & Johnson may not influence the selection of individuals to receive educational support. (Guidance Document on Educational and Research Grants)

<b>Free Goods</b>	Items or services provided without charge and not contingent on the purchase of any other item or service. If any contingency is involved, the transaction is a bundled sale. (Guidance Document on Free Goods, Charitable Contributions and Patient Assistance Programs)
<b>Grant</b>	Funding by Johnson & Johnson for activities of a customer that do not principally benefit Johnson & Johnson – no “unrestricted educational grants.” (Guidance Documents on Arrangements to Obtain Consulting and Services from Customers, and Educational and Research Grants)
<b>HCC</b>	Health Care Compliance.
<b>Honoraria</b>	Amounts paid to a speaker at CME programs. (Guidance Document on Educational and Research Grants)
<b>Independent CME Provider</b>	Organization that sponsors accredited CME programs, which is not a customer. (Guidance Document on Educational and Research Grants)
<b>Independent Contractors</b>	Individual or organization that provides services to an entity but which is not an employee of the entity. (Guidance Document on Arrangements to Obtain Consulting and Other Services from Customers)
<b>Inducement</b>	Any item or service of value which is intended to influence a person to recommend the use of a particular product or service.
<b>Inventory Exchange</b>	Arrangement under which Johnson & Johnson companies may exchange equal values of Johnson & Johnson products for an equal value of competing products currently in a customer's inventory. (Guidance Document on Inventory Exchanges and Conversion Funding)
<b>JJFC</b>	Johnson & Johnson Finance Corporation.
<b>Joint Venture</b>	Common undertaking by two unrelated parties to achieve a common purpose under which both parties take on investment risk. (Guidance Document on Investments in Customer Organizations)
<b>Loaner Program</b>	Program under which Johnson & Johnson companies may offer product on a temporary basis while a like product is being repaired pursuant to a service agreement with Johnson & Johnson. (Guidance Documents on Warranties, and Free Products and Services)
<b>Master Agreement</b>	An agreement between OBI and a select group of suppliers. This agreement defines specific terms and conditions that govern the overall relationship between supplier and customer. The provisions

	contained within the Master Agreement are typically non-project specific.
<b>Nominal Value Item</b>	Items of minimal value such as coffee mugs, notepads, and the like. (Guidance Documents on Educational and Research Grants, Entertainment and Gifts, and Free Goods and Services)
<b>Patient Assistance Program</b>	Charitable program designed to provide free or reduced price products to indigent patients whom otherwise would be unable to afford the cost of needed medical care. Programs which primarily benefit physicians or other customers do not qualify as patient assistance programs. (Guidance Document on Free Goods and Patient Assistance Programs)
<b>Payment Schedule</b>	The timeline of payments that will be made by OBI to the supplier. This timeline may be based upon specific dates, milestones or the delivery of output to OBI.
<b>Preceptorship</b>	Service arrangement in which Johnson & Johnson pays a customer to educate Johnson & Johnson employees concerning the operations of a particular business or industry for the benefit of Johnson & Johnson. (Guidance Document Arrangements to Obtain Consulting and Other Services from Customers)
<b>Remuneration</b>	Anything of value, including cash, free goods, free services, investment opportunities, or billing opportunities.
<b>Replacement Program</b>	Program under which Johnson & Johnson undertakes to provide a free durable product to a customer pursuant to a warranty on a like Johnson & Johnson product previously purchased by the customer. (Guidance Document on Warranties)
<b>Scope of Work</b>	A description of the services or tasks to be performed in as much detail as possible. A project timeline should specify the duration of the arrangement. The scope of work should include performance benchmarks and specific deliverables.
<b>Supplier</b>	An individual or organization that provides goods or services to OBI at a charge.
<b>Totality</b>	The appropriateness of a specific customer relationship with a Johnson & Johnson company must be considered in light of the entire relationship.
<b>Training Program</b>	Program under which Johnson & Johnson trains health care practitioners in the FDA-approved uses of Johnson & Johnson items or services. (Guidance Documents on Arrangements to Obtain Consulting and Other Services from Customers, training Programs, Travel Expense Reimbursement, and Site Visits)

<b>Value Added Item or Service</b>	Free item or service that is provided to a customer in connection with the purchase of a Johnson & Johnson item or service. It is considered part of Johnson & Johnson's ordinary marketing overhead and is commonly offered to preferred customers in connection with the sale of the product. Value-added services are distinguishable from bundled services in that they are not commonly offered separately for sale, but rather are provided to the customer. (Guidance Documents on Consulting and Services Provided to Customers, Computer Hardware and Software, Free Goods and Services Provided to Customers, Computer Hardware and Software, Free Goods and Services, Warranties, and Combined Products and Services)
<b>Warranty</b>	Written guarantee of the integrity of a product and of the maker's responsibility for the repair or replacement of defective parts.